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

In the Matter of the Accusation Against:

LIFE WELLNESS PHARMACY, INC. dba LIFE WELLNESS PHARMACY, INC., PRESIDENT, MICHAEL LENZNER 1932 Kellogg Avenue Carlsbad, CA 92008

Original Pharmacy Permit No. PHY 45971,

MICHAEL LENZNER 6743 Follette Street Carlsbad, CA 92009

Pharmacist License No. RPH 33245,

and

AMANDA L. CANALES, RPH aka AMANDA L. CAMARIGG 31312 Avenida Terramar San Juan Capistrano, CA 92675

Pharmacist License No. RPH 44504

Respondent.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by

the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on October 3, 2008

It is so ORDERED September 3, 2008

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

KÉDÍNETH H. SCHELL Board President

Case No. 3000

OAH No. L-2007080042

By

·	-		
	.1	EDMUND G. BROWN JR., Attorney General of the State of California	
	2	LINDA K. SCHNEIDER	
	2	Supervising Deputy Attorney General	
	3	RITA M. LANE, State Bar No. 171352 Deputy Attorney General	
	4	110 West "A" Street, Suite 1100	
	5	San Diego, CA 92101	
	S	P.O. Box 85266	
	6	San Diego, CA 92186-5266	
	7	Telephone: (619) 645-2614	
	. /	Facsimile: (619) 645-2061	
	8	Attorneys for Complainant	
	9	BEFORE T	THE
		BOARD OF PHA	ARMACY
	10	DEPARTMENT OF CON STATE OF CAL	
	11	STATE OF CAL	IFORMA
	10		
	12	In the Matter of the Accusation Against:	Case No. 3000
	13	LIFE WELLNESS PHARMACY, INC.	OAH No. L-2007080042
·	14	dba LIFE WELLNESS PHARMACY, INC., PRESIDENT, MICHAEL LENZNER	STIPULATED SETTLEMENT AND
		1932 Kellogg Avenue	DISCIPLINARY ORDER
	15	Carlsbad, CA 92008	
	16	Original Pharmacy Permit No. PHY 45971,	
	17	MICHAEL LENZNED	
	17	MICHAEL LENZNER 6743 Follette Street	
	18	Carlsbad, CA 92009	
	19	Pharmacist License No. RPH 33245,	
	20	and	
	21	AMANDA L. CANALES, RPH	
	22	aka AMANDA L. CAMARIGG	
	44	31312 Avenida Terramar San Juan Capistrano, CA 92675	
	23		
	24	Pharmacist License No. RPH 44504	
		Respondents.	
	25		
	26		
	27	IT IS HEREBY STIPULATED AND	O AGREED by and between the parties to the
	28	above-entitled proceedings that the following matter	rs are true:
		1	
		11	

PARTIES

Virginia Herold (Complainant) is the Executive Officer of the Board of
 Pharmacy (Board). She brought this action solely in her official capacity and is represented in
 this matter by Edmund G. Brown Jr., Attorney General of the State of California, by Rita M.
 Lane, Deputy Attorney General.

Michael Lenzner as President of Life Wellness Pharmacy, Inc. dba Life
 Wellness Pharmacy, Inc., and individually (Respondent) is represented in this proceeding by
 attorney Herbert L. Weinberg, whose address is 1800 Century Park East, 8th Floor, Los Angeles,
 CA 90067. Michael Lenzner, as President of Life Wellness Pharmacy, Inc., is duly authorized to
 enter into this Stipulated Settlement on behalf of Life Wellness Pharmacy, Inc. and does so on
 both his own behalf and on behalf of Life Wellness Pharmacy, Inc.

On or about July 12, 2002, the Board issued Original Pharmacy Permit No. 12 3. PHY 45971 to Life Wellness Pharmacy, Inc., d.b.a. Life Wellness Pharmacy, Inc., Michael 13 Lenzner, President (Respondent). The Original Pharmacy permit was in full force and effect at 14 all times relevant to the charges brought herein and will expire on July 1, 2008, unless renewed. 15 On or about August 21, 1979, the Board issued Pharmacist License No. 16 4. 17 RPH 33245 to Michael Lenzner, RPH (Respondent). The license was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2008, unless 18 renewed. At all times relevant herein, Respondent was and is the Pharmacist-in-Charge (PIC) at 19 20 Life Wellness Pharmacy, Inc.

21

1

JURISDICTION

Accusation No. 3000 was filed before the Board, Department of Consumer
Affairs, and is currently pending. The Accusation and all other statutorily required documents
were properly served on Respondent on June 8, 2007. Respondent timely filed his Notice of
Defense contesting the Accusation. A copy of Accusation No. 3000 is attached as Exhibit A and
incorporated herein by reference.

- 27 ///
- 28 ///

ADVISEMENT AND WAIVERS

Respondent has carefully read, fully discussed with counsel, and understands
 the charges and allegations in Accusation No. 3000. Respondent has also carefully read, fully
 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
 Order.

7. Respondent is fully aware of his legal rights in this matter, including the right
to a hearing on the charges and allegations in the Accusation; the right to confront and crossexamine the witnesses against him; the right to present evidence and to testify on his own behalf;
the right to the issuance of subpoenas to compel the attendance of witnesses and the production
of documents; the right to reconsideration and court review of an adverse decision; and all other
rights accorded by the California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

15 9. Respondent admits the truth of each and every charge and allegation in
 16 Accusation No. 3000.

17 10. The admissions made by Respondent herein are only for the purposes of this
18 proceeding, or any other proceedings in which the Board or other professional licensing agency is
19 involved, and shall not be admissible in any other criminal or civil proceeding.

20 11. Respondent agrees that his Original Pharmacy Permit and his Pharmacist
21 License are subject to discipline and he agrees to be bound by the Board's imposition of
22 discipline as set forth in the Disciplinary Order below.

23 24

14

1

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy.
Respondent understands and agrees that counsel for Complainant and the staff of the Board of
Pharmacy may communicate directly with the Board regarding this stipulation and settlement,
without notice to or participation by Respondent or his counsel. By signing the stipulation,
Respondent understands and agrees that he may not withdraw his agreement or seek to rescind

the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt
 this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall
 be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action
 between the parties, and the Board shall not be disqualified from further action by having
 considered this matter.

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

9 14. In consideration of the foregoing admissions and stipulations, the parties
10 agree that the Board may, without further notice or formal proceeding, issue and enter the
11 following Disciplinary Order:

DISCIPLINARY ORDER

13IT IS HEREBY ORDERED that Original Pharmacy Permit No. PHY 4597114issued to Life Wellness Pharmacy, Inc. dba Life Wellness Pharmacy, Inc., is revoked. Said15revocation will become effective 90 days from the effective date of this decision.

12

IT IS FURTHER ORDERED that Pharmacist License No. RPH 33245 issued to
 Michael Lenzner is revoked. However, the revocation is stayed and Respondent is placed on
 probation for five (5) years on the following terms and conditions.

Actual Suspension - Pharmacist. Pharmacist License No. RPH 33245,
 issued to Respondent Michael Lenzner is suspended for a period of one (1) year.

21 During suspension, Respondent shall not enter any pharmacy area or any portion 22 of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other 23 distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous 24 drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, 25 compounding, dispensing or patient consultation; nor shall Respondent manage, administer, or 26 27 be a consultant to any licensee of the Board, or have access to or control the ordering, 28 manufacturing or dispensing of dangerous drugs and devices or controlled substances.

1	Respondent shall not engage in any activity that requires the professional				
2	judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of				
3	pharmacy. <u>Respondent shall not perform the duties of a pharmacy technician or an exemptee for</u>				
4	any entity licensed by the Board. Subject to the above restrictions, Respondent may continue to				
5	own or hold an interest in any pharmacy in which he holds an interest at the time this decision				
6	becomes effective unless otherwise specified in this order.				
7	2. Obey All Laws. Respondent shall obey all state and federal laws and				
8	regulations substantially related to or governing the practice of pharmacy.				
9	Respondent shall report any of the following occurrences to the Board, in writing,				
10	within 72 hours of such occurrence:				
11	• an arrest or issuance of a criminal complaint for violation of any provision of the				
12	Pharmacy Law, state and federal food and drug laws, or state and federal				
13	controlled substances laws				
14	• a plea of guilty or nolo contendere in any state or federal criminal proceeding to				
15	any criminal complaint, information or indictment				
16	• a conviction of any crime				
17	• discipline, citation, or other administrative action filed by any state and federal				
18	agency which involves Respondent's license or which is related to the practice				
19	of pharmacy or the manufacturing, obtaining, handling or distribution or billing				
20	or charging for any drug, device or controlled substance.				
21	3. Reporting to the Board. Respondent shall report to the Board				
22	quarterly. The report shall be made either in person or in writing, as directed. Respondent				
23	shall state under penalty of perjury whether there has been compliance with all the terms and				
24	conditions of probation. If the final probation report is not made as directed, probation shall				
25	be extended automatically until such time as the final report is made and accepted by the				
26	Board.				
27	4. Interview with the Board. Upon receipt of reasonable notice,				
28	Respondent shall appear in person for interviews with the Board upon request at various				

5

II.

intervals at a location to be determined by the Board. Failure to appear for a scheduled
 interview without prior notification to Board staff shall be considered a violation of probation.

5. **Cooperation with Board Staff.** Respondent shall cooperate with the Board's inspectional program and in the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of his probation. Failure to comply shall be considered a violation of probation.

6. Continuing Education. Respondent shall provide evidence of efforts
8 to maintain skill and knowledge as a pharmacist as directed by the Board.

7. Notice to Employers. Respondent shall notify all present and
prospective employers of the decision in case number 3000 and the terms, conditions and
restrictions imposed on Respondent by the decision. Within 30 days of the effective date of
this decision, and within 15 days of Respondent undertaking new employment, Respondent
shall cause his direct supervisor, pharmacist-in-charge and/or owner to report to the Board in
writing acknowledging the employer has read the decision in case number 3000.

15 If Respondent works for or is employed by or through a pharmacy employment
16 service, Respondent must notify the direct supervisor, pharmacist-in-charge, and/or owner at
17 every pharmacy of the and terms conditions of the decision in case number 3000 in advance of
18 the Respondent commencing work at each pharmacy.

"Employment" within the meaning of this provision shall include any full-time, parttime, temporary, relief or pharmacy management service as a pharmacist, whether the
Respondent is considered an employee or independent contractor.

8. No Preceptorships, Supervision of Interns, Being Pharmacist-inCharge (PIC), or Serving as a Consultant. Respondent shall not supervise any intern
pharmacist or perform any of the duties of a preceptor, nor shall Respondent be the
pharmacist-in-charge of any entity licensed by the Board unless otherwise specified in this
order.

27
9. Reimbursement of Board Costs. Respondent shall pay to the Board
28 its costs of investigation and prosecution in the amount of \$14,000. Respondent shall make a

б

partial payment of \$10,000 within 120 days of the effective date of this decision. The 1 remaining \$4,000 payment shall be arranged with the Board. 2

The filing of bankruptcy by Respondent shall not relieve Respondent of his 3 responsibility to reimburse the Board its costs of investigation and prosecution. 4

10. Probation Monitoring Costs. Respondent shall pay the costs 5 associated with probation monitoring as determined by the Board each and every year of 6 probation. Such costs shall be payable to the Board at the end of each year of probation. 7 Failure to pay such costs shall be considered a violation of probation. 8

Status of License. Respondent shall, at all times while on probation, 9 11. maintain an active current license with the Board, including any period during which 10 suspension or probation is tolled. 11

If Respondent's license expires or is cancelled by operation of law or otherwise, 12 13 upon renewal or reapplication, Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied. 14

15

License Surrender while on Probation/Suspension. Following the 12. 16 effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may tender 17 his license to the Board for surrender. The Board shall have the discretion whether to grant 18 the request for surrender or take any other action it deems appropriate and reasonable. Upon 19 formal acceptance of the surrender of the license, Respondent will no longer be subject to the 20 21 terms and conditions of probation.

Upon acceptance of the surrender, Respondent shall relinquish his pocket 22 23 license to the Board within 10 days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three years from the effective 24 date of the surrender. Respondent shall meet all requirements applicable to the license sought 25 as of the date the application for that license is submitted to the Board. 26

27 Notification of Employment/Mailing Address Change. Respondent 13. shall notify the Board in writing within 10 days of any change of employment. Said 28

notification shall include the reasons for leaving and/or the address of the new employer,
 supervisor or owner and work schedule if known. Respondent shall notify the Board in
 writing within 10 days of a change in name, mailing address or phone number.

14. Tolling of Probation. Should Respondent, regardless of residency, for
any reason cease practicing pharmacy for a minimum of 40 hours per calendar month in
California, Respondent must notify the Board in writing within 10 days of cessation of the
practice of pharmacy or the resumption of the practice of pharmacy. Such periods of time
shall not apply to the reduction of the probation period. It is a violation of probation for
Respondent's probation to remain tolled pursuant to the provisions of this condition for a
period exceeding three years.

"Cessation of practice" means any period of time exceeding 30 days in which Respondent is not engaged in the practice of pharmacy as defined in Section 4052 of the Business and Professions Code.

11

12

13

14 15. Violation of Probation. If Respondent violates probation in any 15 respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke 16 probation and carry out the disciplinary order which was stayed. If a petition to revoke 17 probation or an accusation is filed against Respondent during probation, the Board shall have 18 continuing jurisdiction and the period of probation shall be extended, until the petition to 19 revoke probation or accusation is heard and decided.

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

25 16. Completion of Probation. Upon successful completion of probation,
26 Respondent's license will be fully restored.

27 17. Remedial Education. During the period of probation, Respondent
28 shall attend and complete an ethics course to be arranged by the Board and to be completed at

Respondent's own expense. The period of probation shall be extended until such ethics course
 is successfully completed and written proof, in a form acceptable to the Board, is provided to
 the Board. The ethics course shall be in addition to continuing education courses used for
 license renewal purposes. Failure to complete the remedial education as set forth hereinabove
 is grounds for the filing of a petition to revoke probation.

Following the completion of the course, the Board may administer an
examination to test the Respondent's knowledge of the course.

No Ownership of Premises. Respondent shall not own, have any legal
or beneficial interest in, or serve as a manager, administrator, member, officer, director,
associate, or partner of any business, firm, partnership, or corporation currently or hereinafter
licensed by the Board. Respondent shall sell or transfer any legal or beneficial interest in any
entity licensed by the Board within 90 days following the effective date of this decision and
shall immediately thereafter provide written proof thereof to the Board.

14 19. No Employment at a Compounding Pharmacy. Respondent shall
15 not be employed at a compounding pharmacy.

16 20. **Tolling of Suspension.** If Respondent leaves California to reside or 17 practice outside this state, for any period exceeding 10 days (including vacation), Respondent 18 must notify the Board in writing of the dates of departure and return. Periods of residency or 19 practice outside the state - or any absence exceeding a period of 10 days shall not apply to the 20 reduction of the suspension period.

Respondent shall not practice pharmacy upon returning to this state until
notified by the Board that the period of suspension has been completed.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order
and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the
stipulation and the effect it will have on my Original Pharmacy Permit and my Pharmacist
///

28 ///

23

P, 11.

1	License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly,
2	and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.
3	DATED: 5-12-08
4	$\langle \rangle$
5	michael Denne
6	MICHAEL LENZNER, RPH, individually and as PRESIDENT OF LIFE WELLNESS PHARMACY,
7	INC. Respondent
8	
9	I have read and fully discussed with Michael Lenzner, RPH and President of
10	Life Wellness Pharmacy, Inc., the terms and conditions and other matters contained in the
11	above Stipulated Settlement and Disciplinary Order. I approve its form and content.
12	DATED: <u>5-12-08</u>
13	ALTTH/
14	HERBERTYL, WEINBERG
15	Attomey for Respondent
16	
17	ENDORSEMENT
18	The foregoing Stipulated Settlement and Disciplinary Order is hereby
19	respectfully submitted for consideration by the Board of Pharmacy of the Department of
20	Consumer Affairs.
21	DATED: 7-3-08
22	EDMUND G. BROWN JR., Attorney General of the State of California
23	LINDA K. SCHNEIDER
24	Supervising Deputy Attorney General
25	PPA IN MAN
26	RITA M. LANE
27 28	Deputy Attorney General Attorneys for Complainant
20	80237959.wpd
	10
[

May 12 08 08:31p Polly Marks Weinberg

Exhibit A Accusation No. 3000

1	EDMUND G. BROWN JR., Attorney General of the State of California	· · · · · · · · · · · · · · · · · · ·
2	MARGARET A. LAFKO Supervising Deputy Attorney General	
3	RITA M. LANE, State Bar No. 171352 Deputy Attorney General	• · · · · · · · · · · · · · · · · · · ·
4	California Department of Justice	
5	110 West "A" Street, Suite 1100 San Diego, CA 92101	· .
6	P.O. Box 85266	
7	San Diego, CA 92186-5266 Telephone: (619) 645-2614 Facsimile: (619) 645-2061	
8	Attorneys for Complainant	•
9	Anomeys for Complainant	
10	BEFORE T BOARD OF PHA	
11	DEPARTMENT OF CON STATE OF CAL	SUMER AFFAIRS
12	STATE OF CAL	ITORIALA
13	In the Matter of the Accusation Against:	Case No. 3000
14	LIFE WELLNESS PHARMACY, INC.	
15	d.b.a. LIFE WELLNESS PHARMACY, INC. PRESIDENT, MICHAEL LENZNER	ACCUSATION
16	1932 Kellogg Avenue Carlsbad, CA 92008	
17	Original Pharmacy Permit No. PHY 45971,	
18	MICHAEL LENZNER, RPH	
19	6743 Follette St. Carlsbad, CA 92009	
20	Pharmacist License No. RPH 33245,	
21	and	
22	AMANDA L. CANALES, RPH a.k.a. AMANDA L. CAMARIGG	
23	31312 Avenida Terramar San Juan Capistrano, CA 92675	
24	Pharmacist License No. RPH 44504	
25	Respondents.	
26		
27	///	
28	///	

Complainant alleges:

2	PARTIES
3	1. Virginia Herold (Complainant) brings this Accusation solely in her official
4	capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
5	2. On or about July 12, 2002, the Board of Pharmacy issued Original Pharmacy
6	Permit No. PHY 45971 to Life Wellness Pharmacy, Inc., d.b.a. Life Wellness Pharmacy, Inc.,
7	President, Michael Lenzner (Respondent Life Wellness). The Original Pharmacy permit was in
8	full force and effect at all times relevant to the charges brought herein and will expire on July 1,
9	2007, unless renewed.
10	3. On or about August 21, 1979, the Board of Pharmacy issued Pharmacist License
11	No. RPH 33245 to Michael Lenzner, RPH (Respondent Lenzner). The license was in full force
12	and effect at all times relevant to the charges brought herein and will expire on November 30,
13	2008, unless renewed. At all times relevant herein, Lenzner was and is the Pharmacist-in-Charge
14	(PIC) at Respondent Life Wellness.
15	4. On or about August 9, 1991, the Board of Pharmacy issued Pharmacist License
16	No. RPH 44504 to Amanda L. Canales, RPH, a.k.a. Amanda L. Camarigg (Respondent Canales).
17	The license was in full force and effect at all times relevant to the charges brought herein and will
1,8	expire on November 30, 2008, unless renewed.
19	JURISDICTION
20	5. This Accusation is brought before the Board of Pharmacy (Board), Department of
21	Consumer Affairs, under the authority of the following laws of the Business and Professions
22	Code (Code):
23	A. Section 118(b) of the Code provides that the expiration of a license without the
24	written consent of the Board shall not, during any period in which it may be renewed, restored,
25	reissued, or reinstated, deprive the Board of its authority to institute or continue a disciplinary
26	proceeding against a licensee.
27	B. Section 125.3 of the Code states, in pertinent part, that the Board may request the
28	administrative law judge to direct a licentiate found to have committed a violation or violations

	1	of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
	2	enforcement of the case.
	3	C. Section 4022 of the Code states:
	4	"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
	5 6	(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
	. 7	(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ," "Rx only," or words of similar
	8	import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
	9	(c) Any other drug or device that by federal or state law can be lawfully
	10	dispensed only on prescription or furnished pursuant to Section 4006.
	11	D. Section 4052 of the Code states in pertinent part:
	12	(a) Notwithstanding any other provision of law, a pharmacist may:
\sim	13	
	14	(5)(A) Perform the following procedures or functions as part of the care
	15	provided by aphysician, in accordance, as applicable, with policies, procedures, or protocols of thatphysician
	16	
	17	(iv) Initiating or adjusting the drug regimen of a patient pursuant to a
	18	specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the physician. Adjusting the drug regimen does not include substituting or
	19	selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the
	20	appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours."
	21	
	22	E. Section 4059 of the Code states in pertinent part:
	23	(a) A person may not furnish any dangerous drug, except upon the
	24	prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any
	25	dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.
•	26	///
	27	
	28	1. The above provisions are contained currently in Code §4052(a)(5) plus §4052.2(a)(4) and (c)(3).

Section 4063 of the Code states:

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

19

20

21

22

23

24

25

26

27

F.

G.

Section 4081 of the Code states in pertinent 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 any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

Η.

T.

J.

Section 4113 of the Code states in pertinent part:

(b) 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.

18

Section 4115 of the Code states in pertinent part:

(f) The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy technician may perform the duties, as specified in subdivision (a), only under the immediate, personal supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be without the pharmacist's view....

(g)(1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a)...

Section 4156 of the Code states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

		•	
1		K.	Section 4300 of the Code provides in pertinent part that every license issued by
2	the Bo	oard ma	ay be suspended or revoked.
3		L.	Section 4301 of the Code states in pertinent part:
4			The board shall take action against any holder of a license who is guilty of
5		misre	fessional conduct or whose license has been procured by fraud or presentation or issued by mistake. Unprofessional conduct shall include, but limited to, any of the following:
6			
7			
8		the Ui	(j) The violation of any of the statutes of this state, or any other state, or of nited States regulating controlled substances and dangerous drugs.
9			
10		1	(o) Violating or attempting to violate, directly or indirectly, or assisting in
11		chapte	tting the violation of or conspiring to violate any provision or term of this er or of the applicable federal and state laws and regulations governing
12			nacy, including regulations established by the board or by any other state or Il regulatory agency.
13			
14		M.	Section 4342 of the Code states in pertinent part:
15		-	(a) The board may institute any action or actions as may be provided by
16		prepai	nd that, in its discretion, are necessary, to prevent the sale of pharmaceutical rations and drugs that do not conform to the standard and tests as to quality rength, provided in the latest edition of the United States Pharmacopoeia or
17		the Na	ational Formulary, or that violate any provision of the Sherman Food, Drug osmetic Law (Part 5 (commencing with Section 109875) of Division 104 of
18			ealth and Safety Code).
19		6.	This Accusation also refers to the following sections of California Code of
20	Regula	ations, 1	title 16 (CCR):
21		А.	CCR section 1717, states in pertinent part:
22		D ((b) In addition to the requirements of Section 4040, Business and
23 ·		Profes prescr	ssions Code, the following information shall be maintained for each iption on file and shall be readily retrievable:
24		1	(1) The date dispensed, and the name or initials of the dispensing
25		pharm be init	nacist. All prescriptions filled or refilled by an intern pharmacist must also tialed by the supervising pharmacist before they are dispensed.
26		diana	(2) The brand name of the drug or device; or if a generic drug or device is nsed, the distributor's name which appears on the commercial package label;
27		disper and	iscu, me uismoutor s name which appears on me commercial package laber,
28	///		
	l		

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

B. CCR section 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

C.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

CCR section 1716.2 states in pertinent part:

(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:

(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.

(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.

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

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

27 || ///

28 ///

.1	D. CCR section 1761 states:
2	(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or
3	alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
4	(b) Even after conferring with the prescriber, a pharmacist shall not
5	compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a
6	legitimate medical purpose.
.7	7. This Accusation also refers to the following sections of the Health & Safety Code
8	(H&S Code):
9	A. H&S Code section 11164 states:
10	Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a
11	prescription for a controlled substance, unless it complies with the requirements of this section.
12	(a) Each prescription for a controlled substance classified in Schedule II,
13	III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall
14	meet the following requirements:
15	(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the
16	ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill
17 18	information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
19	(2) The prescription shall also contain the address of the person for whom
20	the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the
21	prescription or maintain this information in a readily retrievable form in the pharmacy.
22	(b)(1) Notwithstanding paragraph (1) of subdivision (a) of Section
23	11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be
24	produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the
25	Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity,
26	authority, and confidentiality of the prescription.
27	(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record
28	of the prescription; the pharmacist need not include the address, telephone

number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

10

11

12

13

14

17

18

19

20

21

22

23

24

26

1

2

3

4

5

6

7

8

9

H&S Code section 11200 states:

(a) No person shall dispense or refill a controlled substance prescription more than six months after the date thereof.

(b) No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply.

15

This Accusation also refers to Code of Federal Regulations, title 21, section

16 || 310.515(a) that states:

8.

Β.

(a) Requirement for a patient package insert. FDA concludes that the safe and effective use of drug products containing estrogens requires that patients be fully informed of the benefits and risks involved in the use of these drugs. Accordingly, except as provided in paragraph (e) of this section [not relevant here], each estrogen drug product restricted to prescription distribution, including products containing estrogens in fixed combinations with other drugs, shall be dispensed to patients with a patient package insert containing information concerning the drug's benefits and risks. An estrogen drug product that does not comply with the requirements of this section is misbranded under section 502(a) of the Federal Food, Drug, and Cosmetic Act.

DRUGS

25 to Code section 4022.

9.

10. T-3 is a name for Triiodo-L-Thyronine, a thyroid hormone and a dangerous drug

T-4 is a name for L-Thyroxine, a thyroid hormone and a dangerous drug pursuant

27 || pursuant to Code section 4022.

28 || ///

Biest is a brand name for estriol + estradiol that are estrogens and dangerous drugs
 pursuant to Code section 4022.
 Testosterone is an androgen hormone. It is a Schedule II controlled substance
 pursuant to H&S Code section 11056 and a dangerous drug pursuant to Code section 4022.
 Progesterone is a hormone and a dangerous drug pursuant to Code section 4022.

6 14. Armour Thyroid is T-3/T-4 in fixed ratio and is a dangerous drug pursuant to
7 Code section 4022.

8 15. Triest is a brand name for estriol + estradiol + estrone that are estrogens and
9 dangerous drugs pursuant to Code section 4022.

10 11

12

CHARGES AND ALLEGATIONS

<u>RESPONDENT MICHAEL LENZNER, RPH</u>

First Cause for Discipline

(Unprofessional Conduct: Prescribing & Furnishing Prescriptions for Dangerous Drugs 13 Without an Authorized Prescription & Without Written Policies, Procedures, or Protocols) 14 Respondent Lenzner, RPH is subject to disciplinary action under sections 4301(o) 15 16. in conjunction with section 4052(a)(5)(A)(iv) because Lenzner initiated prescriptions that were 16 furnished at Life Wellness for drug regiments for patients without policies, procedures, or 17 protocols and without a prescription from a licensed prescriber as specified in the Business and 18 Professions Code Section 4052 (a)(5)(A)(iv). The following prescriptions were written by 19 Lenzner and dispensed at Life Wellness without an authorized prescription and without written 20 policies, procedures or protocol from a physician: 21

A. For E.D. of Hollywood, Florida - On 4/16/04, two prescriptions were prescribed and
written by Lenzner for this customer for Biest (70/30) 1.25mg + Progesterone 40mg Cream and
for Estriol 2mg Vaginal Cream, that were not signed by the prescriber physician. The subsequent
dispensing and furnishing from Life Wellness Pharmacy on RX 103490 for 30gm-Biest (70/30)/
Progesterone 1.25mg/40mg Cream and RX 103492 for 24gm-Estriol 0.2% Vaginal Cream was
without authorization.

28 ///

B. For T.L. of San Bernardino, California - On 7/5/04, a prescription was prescribed and
 written by Lenzner for this customer that was not signed by a physician. The subsequent
 dispensing and furnishing at Life Wellness Pharmacy on RX 104801 for 15gm of Progesterone
 5% Cream was without authorization.

C. For C.D. of San Diego, California - On 11/4/04, a prescription was prescribed and
written with 3 refills by Lenzner for this customer for Biest (80/20) 2.5mg + Progesterone 40mg
+ Testosterone 0.5mg Cream (a schedule III controlled substance) that was not signed by a
physician. The subsequent dispensing and furnishing from Life Wellness Pharmacy on RX
106634 for 30gm-Biest (80/20) 2.5mg + Progesterone 40mg + Testosterone 0.5mg Cream (a
schedule III controlled substance) was without authorization.

11

12

Second Cause for Discipline

(Unprofessional Conduct: Dispensing Controlled Substances Without a Prescription)

17. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(j)
and 4113(b) in conjunction with sections 4059 and H&S Code section 11164, because pharmacy
staff dispensed controlled substances without a prescription as follows:

A. For R.D.L. of San Diego, California - on 1/5/04, RX C101017 was updated to RX
C102476 but not re-written, and there are no written documents authorizing the dispensing of
30gm-Testosterone 0.4% Cream. On 7/20/04, RX C102476 was updated to RX C104779 but not
re-written, and there were no written documents authorizing the dispensing of 30gm-

20 Testosterone 0.4% Cream.

B. For C. D.M. of Fullerton, California - there were no signed documents authorizing the
initial dispensing of this customer's 30gm-Testosterone 10%Cream on prescription RX 100196
for 2/3/03, and there was no re-written documentation or authorization for the subsequent
dispensing on the updated prescriptions RX 100899 on 6/5/03 and again on the updated
prescription RX 105032 on 8/2/04.

- 26 ///
- 27 ///
- 28 ///

Third Cause for Discipline

(Unprofessional Conduct: Dispensing a Dangerous Drug Without a Prescription)
18. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o)
in conjunction with section 4059 because he, either directly as the dispensing pharmacist or as
the PIC in conjunction with section 4113(b), is responsible for the unauthorized dispensing of
dangerous drugs without a prescription at Life Wellness Pharmacy by pharmacist Amanda
Canales (formerly Camarigg) as follows:

For R.D.L. of San Diego, California - On 6/21/04, Rx 101016 was updated to RX A. 8 104240 for this customer's 30m-Triest (70-20-10)/Progesterone 2.5mg/100mg Cream, but there 9 was no documentation or written prescription record authorizing the dispensing and furnishing. 10 For S.D. of Olivenhain, California - On 2/13/03, an unsigned medication order for B. 11 S.D. from a naturopathic doctor requested Life Wellness Pharmacy to compound a combination 12 of T-4/T-3 as T-4 as 9.5mcg and T-3 as 2.5mcg which was errantly compounded, dispensed and 13 furnished on RX 100233. 14

C. For R.D. of Trabuco Canyon, California - On 8/10/04, an unsigned prescription
was written by a naturopathic doctor for this customer for 30gm Estriol Vaginal Cream
0.5mg/gm with 3 refills. It was dispensed and furnished on 8/11/04 on prescription number RX
105200 with the prescriber labeled both as the naturopathic doctor and a physician, but the
prescription order from the naturopathic doctor was not signed by the named physician or any
other licensed prescriber.

- D. For S.D. of Coronado, California On 10/6/04, two unsigned prescriptions were written by a naturopathic doctor for this customer for #30 Armour Thyroid 60mg (1gr) and #30 Armour Thyroid 15mg (¼ gr). They were dispensed and furnished by PIC Lenzner on 10/7/04 on RX 106327 for Armour Thyroid ¼ gr and on RX 106328 for Armour Thyroid 1gr with the prescriber labeled both as the naturopathic doctor and a physician, but the prescription order from the naturopathic doctor was not signed by the named physician or any other licensed prescriber.
- 27 ///

1

28 || ///

Fourth Cause for Discipline

1	Fourth Cause for Discipline
2	(Unprofessional Conduct: Unauthorized Refill Prescription Dispensing)
3	19. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o)
4	and 4113(b) in conjunction with section 4063 for the dispensing of unauthorized refill
5	prescriptions, as more particularly alleged below:
6	A. For G.D. of New Vernon, New Jersey - On 9/30/04, RX 105173 for 30gm-
7	Progesterone 4% Cream for this customer was dispensed without authorization.
8	B. For D.D. of Holtsville, New York - On 1/20/05, RX C107103 for Biest (80/20)
9	1.25mg + Progesterone 40mg + Testosterone 0.5mg (a schedule III controlled substance) was
10	dispensed without authorization and shipped to this customer in Clearwater Florida.
11	C. For E.D. of Hollywood, Florida - The refills for this customer on RX 103490 for
12	30gm of Biest (70/30) /Progesterone 1.25mg/40mg were refilled without authorization on
13	5/25/04, 5/27/04, 6/24/04, 7/20/04, 8/30/04, and 9/23/04 and on RX 103492 for 24gm Estriol
14	0.2% Vaginal Cream were dispensed without authorization on 6/24/04 and 8/30/04.
15	D. For C.D.L. of San Clemente, California - On 12/23/04, the refill for this customer
16	for prescription RX 106494 for 30gm-Biest (80/20)/DHEA/Testosterone 1.25/10/2mg/gm Cream
17	(containing a schedule III controlled substance) was dispensed without authorization.
.18	E. For R.D.L. of San Diego, California - The refills for this customer for 30gm-
19	Testosterone 0.4% Cream on RX C102476 for 6/1/04 and 6/21/04 and on RX C104799 for
20	8/18/04 for the schedule III controlled substance and for 30m-Triest (70-20-10)/Progesterone
21	2.5mg/100mg Cream on RX104240 for 7/20/04 and 8/18/04 were dispensed without
22	authorization.
23	F. For C.D.M. of Fullerton, California - There were no written documents
24	authorizing the refill dispensing of this customer's 30gm-Testosterone 10% Cream for
25	prescription RX 100196 on 3/11/03, 4/7/03, and 5/1/0; for prescription RX 100899 on 7/3/03,
26	8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and 6/2/04; and for prescription RX 105032 on
27	9/30/04, 11/29/04, and 2/5/05 for the schedule III controlled substance.
28	
· · •	

For M.D. of San Diego, California - On 1/19/05, the refill for this customer on RX G. 1 106996 for Progesterone 3% Cream was refilled without authorization. 2 For C.D. of San Diego, California -The refills for this customer on RX 106634 for H. 3 Biest (80/20) 2.5mg + Progesterone 40mg + Testosterone 0.5mg Cream (a schedule III controlled 4 substance) on 12/3/04, 1/6/05, and 2/9/05 were dispensed without authorization. 5 For E.D.R. of Port Jefferson, New York -The refills for this customer on RX T 6 104332 for 15gm Progesterone 5% Cream on 11/8/04 and 12/20/04 were dispensed without 7 authorization. 8 For A.D.P. of San Diego, California -The refills for this customer on RX 103685 J. 9 for 1-30gm Progesterone 6% Cream dispensed on 8/26/04, for 2-30gm Progesterone 6% Cream 10 dispensed on 10/25/04, and for 2-30gm Progesterone 6% Cream dispensed on 1/27/05 were 11 dispensed without authorization. 12

13K.For R.D. of Trabuco Canyon, California - On 10/15/04, the refill for this customer14on RX 105200 for Estriol Vaginal Cream 0.5mg was dispensed without authorization.

L. For L.D. of Port Jefferson, New York - The refills for this customer dispensed on
11/22/04 and 12/21/04 for RX 106461 for 15gm of Progesterone 3% Cream and for RX 106462
for #60 T-3 SR 5mcg capsules were dispensed without authorization.

M. For T.L. of San Bernardino, California - The refills for this customer dispensed on
8/24/04, 9/24/04, 10/18/04, 11/15/04, and 1/25/05 for 15gm of Progesterone 5% Cream were
dispensed without authorization.

21

22

Fifth Cause for Discipline

(Unprofessional Conduct: Dispensing of Medications of Uncertain Strength)

20. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o)
in conjunction with CCR section 1761(a) because Lenzner dispensed a prescription of uncertain
strength in that he dispensed a prescription which contained a significant error, omission,
inregularity, uncertainty, or alteration. Specifically, on 9/7/04 at Life Wellness, a prescription of
T-3 was compounded using the compounding lot # <u>09072004@6</u> for the T-3 SR 7.5 mg capsules
for customer S.D. of San Diego, California on RX 105840. This compound record was missing

during the Board's investigation, yet the customer's Universal Claim Form for a Compounded
Medication prepared by Life Wellness on 9/7/04 showed the strength of the T-3 SR 7.5mcg
capsules contained a 500% error. Additionally, the T-3 1:10 triturate used to compound the T-3
SR 7.5mcg capsules showed an errant triturate formula and calculations on their logged formula
worksheets dated 6/30/04 and 1/12/05 and the expiration date placed on the prescription label for
RX 105840 exceeded the 180 day limit.

7

Sixth Cause for Discipline

(Unprofessional Conduct: Incomplete & Erroneous Compounding Records for Future Use) 8 PIC Respondent Lenzner is subject to disciplinary action under sections 4301(0) 21. 9 and 4113(b) in conjunction with CCR section 1716.2(a)(2),(3),(4),(6), and (8) in that a pharmacy, 10 for the purpose of compounding for future dispensing, shall maintain records that include (2) the 11 manufacturers lot number and expiration dates, (3) the expiration date not to exceed 180 days or 12 the shortest expiration date of any component in the finished product, (4) signature or initials of 13 the compounding pharmacist, (6) manufacturer's name of the raw ingredients, (8) package sized 14 and the number of units prepared. Specifically, on 2/16/05 and on 3/11/05, during the complaint 15 investigation at Life Wellness, many of the logged formula worksheets lacked the manufacturer's 16 lot number and expiration dates; gave a one year expiration date to a finished compound instead 17 of 180 days or the shortest expiration date of the ingredients; the compounding pharmacist failed 18 to sign or initial the logged formula worksheet; the manufacturer's name of the active chemicals 19 was omitted or inconsistent with inventory; and the units prepared were inaccurate. Furthermore, 20 the pharmacy was compounding dangerous drugs from formulas containing errors that were 21 noted in the Biest (80-20)/Prog/Test 0.625/50/1Cream and the stock formula called Tri-iodo-L-22 Thyronine (T3) 1:10 Triturate 10mg:1mg powder dated 6/30/04 and 1/12/05. 23

24

Seventh Cause for Discipline

(Unprofessional Conduct: Non-compliance With Maintaining Prescription Records)
 22. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o)
 and 4113(b) in conjunction with CCR section 1717(b) because he failed to maintain complete
 and readily retrievable prescription records. The date dispensed and the name or initials of the

dispensing pharmacist shall be on each prescription on file and readily retrievable. Specifically,
 on 2/16/05, 3/11/05, and 3/15/05, during the complaint investigation at Life Wellness,
 pharmacists did not initial the prescription documents or refill logs to identify the dispensing
 pharmacist, and the initials in the patient's drug history do not represent the actual dispensing
 pharmacist, (e.g., Amanda Camarigg's initials recorded on all new and refilled prescriptions in
 the computer for 3/11/05 but another pharmacist was the only pharmacist working on 3/11/05.)
 <u>Eighth Cause for Discipline</u>

8

9

10

11

12

13

14

23. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o), 4113(b), and 4115(f) and (g) because Lenzner was not compliant with the supervision of pharmacy technicians in that the performance of duties of a pharmacy technician shall be under the direct supervision and control of a pharmacist (§4115(f)) and a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing certain tasks (§4115(g)). Specifically, on 3/11/05 and again on 3/15/05 at Life Wellness, Lenzner scheduled

(Unprofessional Conduct: Non-compliance With Pharmacy Technician Supervision)

only one pharmacist on duty to supervise two pharmacy technicians who were both compoundingand filling prescriptions.

17

18

19

Ninth Cause for Discipline

(Unprofessional Conduct: Non-compliance with Patient Package Inserts for Estrogen Drug Products)

24. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o),
4113(b) and Title 21 Code of Federal Regulations section 310.515(a) because at Life Wellness he
failed to provide patient package inserts for compounded estrogen drug products required by
Code of Federal Regulations, title 21, section 310.515(a). Specifically, during the inspections at
Life Wellness, Lenzner stated on two separate occasions that he does not supply patient package
inserts to patients receiving estrogen products compounded at the pharmacy.

26 ///

27 || ///

28 || ///

Tenth Cause for Discipline

(Unprofessional Conduct: Missing Disposition Records of Dangerous Drugs)
25. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o)
and 4113(b) in conjunction with section 4081(a) because Lenzner failed to maintain all
prescription records as to disposition of dangerous drugs, as required by section 4081(a), as more
particularly alleged below:

A. E.D.'s prescriptions - there were no disposition documents to substantiate the
dispensing on 5/25/04 and 10/29/04 as noted in the patient profile for this customer for RX
103490.

B. R.D.L.'s original prescription for 30gm-Testosterone 0.4% Cream was dispensed
on 6/18/03 on RX C101017 and then was updated on 1/5/04 to RX C102476, but there was no
new written prescription document in this customer's chart. Then RX C102476 was updated on
7/20/04 to RX C104799 but there is no new written prescription document in the chart.
Furthermore, the original prescription for 30m-Triest (70-20-10)/Progesterone 2.5mg/100mg
Cream was dispensed on 6/18/03 and then was updated on 6/21/04 to RX104240, but there is no
new re-written prescription in this customer's chart.

C.D.M.'s original prescription document was not signed by his physician yet C. 17 30gm-Testosterone 10% (100mg/gm) Cream was dispensed on RX 100196 on 2/3/03, 3/11/03, 18 4/7/03 and 5/1/03 until RX 100196 was updated to RX 100899. There was no new re-written or 19 original prescription documents to substantiate the dispensing of RX100899 for the Testosterone 20 10% (100mg/gm) Cream filled on 6/5/2003, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, 21 and 6/2/04 until RX 100899 was updated to 105032, and there is no new re-written or original 22 prescription documents to substantiate the dispensing of RX105032 for the Testosterone 10% 23 (100mg/gm) Cream filled on 8/2/04, 9/30/04, 11/29/04, and 2/5/05. 24

25

1

Eleventh Cause for Discipline

26 (Unprofessional Conduct: Practice in Violation of H&S Code section 11200)
 27 26. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(j)
 28 and 4113(b) in conjunction with H&S Code section 11200(a) and (b) because Lenzner is

	2 month 3 (b). Sp 4 (100m 5 RX 10 6 6/2/04 7 8 9 0 in conj	asible for the pharmacy staff dispensing controlled substance prescriptions beyond six s and exceeding five refills, as specified in Health and Safety Code Section 11200(a) & pecifically, the dispensing records for customer C.D.M.'s 30gm-Testosterone 10% g/gm) Cream were without prescription documents or authorization records but showed 0899 was dispensed on 6/5/03, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and , which exceeds the five refill maximum and is beyond six months. <u>Twelfth Cause for Discipline</u> (Unprofessional Conduct: Dispensing Error) 27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o) unction with CCR sections 1716 and 1761 in that no pharmacist shall dispense any
	2 month 3 (b). Sp 4 (100m 5 RX 10 6 6/2/04 7 8 9 0 in conj	s and exceeding five refills, as specified in Health and Safety Code Section 11200(a) & becifically, the dispensing records for customer C.D.M.'s 30gm-Testosterone 10% g/gm) Cream were without prescription documents or authorization records but showed 0899 was dispensed on 6/5/03, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and , which exceeds the five refill maximum and is beyond six months. <u>Twelfth Cause for Discipline</u> (Unprofessional Conduct: Dispensing Error) 27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o)
	2 month 3 (b). Sp 4 (100m 5 RX 10 6 6/2/04 7 8 9 0 in conj	s and exceeding five refills, as specified in Health and Safety Code Section 11200(a) & becifically, the dispensing records for customer C.D.M.'s 30gm-Testosterone 10% g/gm) Cream were without prescription documents or authorization records but showed 0899 was dispensed on 6/5/03, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and , which exceeds the five refill maximum and is beyond six months. <u>Twelfth Cause for Discipline</u> (Unprofessional Conduct: Dispensing Error) 27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o)
	2 month 3 (b). Sp 4 (100m 5 RX 10 6 6/2/04 7 8 9 0 in conj	s and exceeding five refills, as specified in Health and Safety Code Section 11200(a) & becifically, the dispensing records for customer C.D.M.'s 30gm-Testosterone 10% g/gm) Cream were without prescription documents or authorization records but showed 0899 was dispensed on 6/5/03, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and , which exceeds the five refill maximum and is beyond six months. <u>Twelfth Cause for Discipline</u> (Unprofessional Conduct: Dispensing Error) 27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o)
	 3 (b). Sp 4 (100m) 5 RX 10 6 6/2/04 7 8 9 0 in conj 	 becifically, the dispensing records for customer C.D.M.'s 30gm-Testosterone 10% g/gm) Cream were without prescription documents or authorization records but showed 0899 was dispensed on 6/5/03, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and which exceeds the five refill maximum and is beyond six months. <u>Twelfth Cause for Discipline</u> (Unprofessional Conduct: Dispensing Error) 27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o)
	4 (100m 5 RX 10 6 6/2/04 7 8 9 0 in conj	 g/gm) Cream were without prescription documents or authorization records but showed 0899 was dispensed on 6/5/03, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and , which exceeds the five refill maximum and is beyond six months. <u>Twelfth Cause for Discipline</u> (Unprofessional Conduct: Dispensing Error) 27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(0)
	5 RX 10 6 6/2/04 7 8 9 0 in conj	 0899 was dispensed on 6/5/03, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and which exceeds the five refill maximum and is beyond six months. <u>Twelfth Cause for Discipline</u> (Unprofessional Conduct: Dispensing Error) 27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(0)
	 6 6/2/04 7 8 9 0 in conj 	 , which exceeds the five refill maximum and is beyond six months. <u>Twelfth Cause for Discipline</u> (Unprofessional Conduct: Dispensing Error) 27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(0)
	7 8 9 0 in conj	<u>Twelfth Cause for Discipline</u> (Unprofessional Conduct: Dispensing Error)27.27.Respondent Lenzner, RPH is subject to disciplinary action under section 4301(0)
	8 9 0 in conj	 (Unprofessional Conduct: Dispensing Error) 27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(0)
	9 0 in conj	27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o)
	0 in conj	
	Ĩ	unction with CCR sections 1716 and 1761 in that no pharmacist shall dispense any
	1 prescri	· · · · · · · · · · · · · · · · · · ·
		ption which contains any significant error, omission, irregularity, uncertainty, or
1	2 alterati	ons. Specifically, on 2/13/03 at Life Wellness Pharmacy, an unsigned medication order
1	3 for S.I). from a naturopathic doctor requested Life Wellness to compound T-4/T-3 in the ratio
]	4 and str	engths of T-4 as 9.5mcg and T-3 as 2.5mcg but the pharmacy dispensed on $2/13/04$ on RX
]	5 100233	3 the compounded formulation as T-3 as 2.5mcg and T-4 as 25mcg. When a physician did
1	6 sign th	e medication order the following day on 2/14/03, that physician did not change the original
1	7 medica	ation order request.
1	8	RESPONDENT AMANDA L. CANALES
	9	Thirteenth Cause for Discipline
-	.0 (Ung	professional Conduct: Prescribing & Furnishing Prescriptions for Dangerous Drugs
. r	1 Witho	ut an Authorized Prescription & Without Written Policies, Procedures, or Protocols)
	.2	28. Respondent Amanda Canales (formerly Camarigg), RPH is subject to disciplinary
	.3 action	under sections 4301(0) in conjunction with section 4052(a)(5)(A)(iv), because she
,	4 initiate	d prescriptions that were furnished at Life Wellness Pharmacy for drug regiments for
,		s without policies, procedures, or protocols and without a prescription from a licensed
		ber, as more particularly alleged below:
·*	27	A. For M.D. of San Diego, California - On 12/15/04, a prescription was prescribed
		ritten by Amanda Camarigg and dispensed at Life Wellness Pharmacy for this customer for

Progesterone 3% Cream on prescription number RX 106997 that was not signed by an authorized
 prescriber, and there was no documented authorization from a prescriber.

B. For L.D. of Port Jefferson, New York - On 10/19/04, two prescriptions were
prescribed and written by Amanda Camarigg for this customer that were not signed by a
physician; on 10/20/04 RX 106461 for 15gm of Progesterone 3% Cream and RX 106462 for #60
T-3 SR 5mcg capsules were dispensed and furnished to this customer without authorization until
a 1/12/05 fax request, which resulted in a physician signing and erroneously dating it as
10/20/05.

C. For D. D. of Holtsville, New York - On 12/21/04 a new prescription was
prescribed and written by Amanda Camarigg that changed the Biest (80/20) 2.5mg to Biest
(80/20) 1.25mg in the compounded prescription of Biest (80/20) 1.25mg + Progesterone 40mg +
Testosterone 0.5mg (a schedule III controlled substance). This was dispensed on RX C107103,
which was unsigned and without a prescriber's name, signature, DEA number, or agent on the
document.

D. For C.D.L. of San Clemente, California - On 10/19/04, two new prescriptions
were prescribed and written by Amanda Camarigg for this customer: on 10/25/04, the first fax for
authorization was sent to a physician, but the two prescriptions were dispensed without
authorization that day on RX 106494 for 30gm-Biest(80/20)/DHEA/Testosterone
1.25/10/2mg/gm Cream (a schedule III controlled substance) and on RX 106493 for 15gmProgesterone 3% Cream.

21

23

22

RESPONDENT LIFE WELLNESS PHARMACY, INC.

Fourteenth Cause for Discipline

(Liability of Life Wellness Pharmacy, Inc.)

24 29. Respondent Life Wellness Pharmacy, Inc. is subject to disciplinary action under
25 section 4156 based on the acts and omissions alleged above in paragraphs 16 through 28, which
26 are realleged and incorporated herein by reference.

27 ///

28 ///

·			
		1	PRAYER
		2	WHEREFORE, Complainant requests that a hearing be held on the matters herein
		3	alleged, and that following the hearing, the Board of Pharmacy issue a decision:
		4	1. Revoking or suspending Original Pharmacy Permit No. PHY 45971, issued to Life
		5	Wellness Pharmacy, Inc., d.b.a. Life Wellness Pharmacy, Inc., President, Michael Lenzner;
		6	2. Revoking or suspending Pharmacist License No. RPH 33245, issued to Michael
		7	Lenzner, RPH;
		8	3. Revoking or suspending Pharmacist License No. RPH 44504, issued to Amanda L.
•		9	Canales, RPH, a.k.a. Amanda L. Camarigg;
		10	4. Ordering Life Wellness Pharmacy, Inc., and/or Michael Lenzner, RPH,
		11.	individually, and Amanda Canales to pay the Board of Pharmacy the reasonable costs of the
		12	investigation and enforcement of this case, pursuant to Business and Professions Code section
	10 10 10	13	125.3; and
•	4 - 1 ²	14	5. Taking such other and further action as deemed necessary and proper.
		15	DATED: 6/6/07
•		16	
•		17	
	۰	18	Ligna Led
		19	VIRGINIA HEROLD / / Executive Officer
		20	Board of Pharmacy Department of Consumer Affairs
		21	State of California Complainant
ι.		22	
		23	
		24	
· .		25	
		26	SD2006801263
		27	80131500.wpd
		28	

.