

1 XAVIER BECERRA
Attorney General of California
2 ANTOINETTE B. CINCOTTA
Supervising Deputy Attorney General
3 MARICHELE S. TAHIMIC
Deputy Attorney General
4 State Bar No. 147392
600 West Broadway, Suite 1800
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 738-9435
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 5989

12 **RELY ON PHARMACY, INC.,**
DBA VALUE CARE PHARMACY; DANIEL
13 **ROJAS, PRESIDENT/CEO; THOMAS V.**
14 **KURIEN, SECRETARY AND**
TREASURER/CFO
15 **1045 N Shepard St**
Anaheim, CA 92805

A C C U S A T I O N

16 **Pharmacy Permit No. PHY 54247**
17 **(formerly Pharmacy Permit No. PHY44873)**

18 and

19 **AMIE VANAHN TONNU**
20 **5 Tanglewood**
Aliso Viejo, CA 9265

21 **Pharmacist License No. RPH 51367**

22 and

23 **THOMAS V. KURIEN**
24 **3105 Claremore Avenue**
Long Beach, CA 90808

25 **Pharmacist License No. RPH 45201**

26 and

27 **///**

28

1 **DANIEL ROJAS**
2 **57 Declaration Pl.,**
3 **Irvine, CA 92602**

4 **Pharmacy Technician Registration No. TCH 4571**

5 Respondents.

6 Complainant alleges:

7 **PARTIES**

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

10 2. On or about July 20, 2000, the Board issued Pharmacy Permit Number PHY 44873 to
11 Rely On Pharmacy, Inc., dba Value Care Pharmacy (Respondent Value Care) at 17662 Irvine
12 Blvd., No. 14, Tustin, California, 92780. Daniel Rojas was President and CEO of Respondent
13 Value Care from July 20, 2000 to April 7, 2016. Thomas V. Kurien is, and has been, the
14 Secretary and Treasurer/Chief Financial Officer of Respondent Value Care since April 5, 2016.
15 Amie Vananh Tonnu, was the Pharmacist-in-Charge from July 20, 2000 to April 7, 2016.
16 Pharmacy Permit No. 44873 was in full force and effect at all times relevant to the charges and
17 was cancelled on April 5, 2016, pursuant to a change of location.

18 3. On or about April 5, 2016, the Board issued Pharmacy Permit Number PHY 54247 to
19 Respondent Value Care at 1045 N. Shepard Street, Anaheim, California, 92805. Daniel Rojas is
20 and has been President and CEO of Respondent Value Care since April 5, 2016. Thomas V.
21 Kurien is, and has been, the Secretary and Treasurer/Chief Financial Officer of Respondent Value
22 Care since April 5, 2016. Amie Vananh Tonnu, is and has been, the Pharmacist-in-Charge since
23 April 5, 2016. Pharmacy Permit No. 54247 was in full force and effect at all times relevant to the
24 charges brought herein and will expire on April 1, 2017, unless renewed.

25 4. On or about March 27, 1992, the Board issued Pharmacist License Number RPH
26 45201 to Thomas V. Kurien (Kurien). The Pharmacist License was in full force and effect at all
27 times relevant to the charges brought herein and will expire on January 31, 2018, unless renewed.

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1 Government Code, and the board shall have all the powers granted therein. The
2 action shall be final, except that the propriety of the action is subject to review by
the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

3 9. Code section 4300.1 states:

4 The expiration, cancellation, forfeiture, or suspension of a board-issued license by
5 operation of law or by order or decision of the board or a court of law, the
6 placement of a license on a retired status, or the voluntary surrender of a license by
a licensee shall not deprive the board of jurisdiction to commence or proceed with
7 any investigation of, or action or disciplinary proceeding against, the licensee or to
render a decision suspending or revoking the license.

8 **STATUTORY AND REGULATORY PROVISIONS**

9 10. Section 4022 of the Code states

10 "Dangerous drug" or "dangerous device" means any drug or device unsafe for
11 self-use in humans or animals, and includes the following:

12 (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing
without prescription," "Rx only," or words of similar import.

13 (b) Any device that bears the statement: "Caution: federal law restricts this device
14 to sale by or on the order of a _____," "Rx only," or words of similar import,
the blank to be filled in with the designation of the practitioner licensed to use or
15 order use of the device.

16 (c) Any other drug or device that by federal or state law can be lawfully dispensed
only on prescription or furnished pursuant to Section 4006."

17 11. Code section 4081 states in part:

18 (a) All records of manufacture and of sale, acquisition, receipt, shipment, or
19 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
20 preserved for at least three years from the date of making. A current inventory shall
be kept by every manufacturer, wholesaler, third-party logistics provider,
21 pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician,
dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or
22 establishment holding a currently valid and unrevoked certificate, license, permit,
registration, or exemption under Division 2 (commencing with Section 1200) of
23 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
24 dangerous drugs or dangerous devices.

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12. Code section 4104 states in part:

...

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

...

13. Code section 4105 states in part:

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form. ...

14. Section 4113 of the Code states in part, "(c) 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. ..."

15. Section 4115 of the Code states in part:

...

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

...

16. Code section 4301 states:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(c) Gross negligence.

...

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

...

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

3 ...

4 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
5 abetting the violation of or conspiring to violate any provision or term of this
6 chapter or of the applicable federal and state laws and regulations governing
7 pharmacy, including regulations established by the board or by any other state or
8 federal regulatory agency. ...

9 17. Code section 4307 states:

10 (a) Any person who has been denied a license or whose license has been revoked
11 or is under suspension, or who has failed to renew his or her license while it was
12 under suspension, or who has been a manager, administrator, owner, member,
13 officer, director, associate, partner, or any other person with management or
14 control of any partnership, corporation, trust, firm, or association whose
15 application for a license has been denied or revoked, is under suspension or has
16 been placed on probation, and while acting as the manager, administrator, owner,
17 member, officer, director, associate, partner, or any other person with management
18 or control had knowledge of or knowingly participated in any conduct for which
19 the license was denied, revoked, suspended, or placed on probation, shall be
20 prohibited from serving as a manager, administrator, owner, member, officer,
21 director, associate, partner, or in any other position with management or control of
22 a licensee as follows:

23 (1) Where a probationary license is issued or where an existing license is
24 placed on probation, this prohibition shall remain in effect for a period not to
25 exceed five years.

26 (2) Where the license is denied or revoked, the prohibition shall continue
27 until the license is issued or reinstated.

28 (b) "Manager, administrator, owner, member, officer, director, associate, partner,
or any other person with management or control of a license" as used in this
section and Section 4308, may refer to a pharmacist or to any other person who
serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant
to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the
Government Code. However, no order may be issued in that case except as to a
person who is named in the caption, as to whom the pleading alleges the
applicability of this section, and where the person has been given notice of the
proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of
Division 3 of the Government Code. The authority to proceed as provided by this
subdivision shall be in addition to the board's authority to proceed under Section
4339 or any other provision of law.

18. Code section 4342 states in part:

(a) The board may institute any action or actions as may be provided by law and
that, in its discretion, are necessary, to prevent the sale of pharmaceutical
preparations and drugs that do not conform to the standard and tests as to quality
and strength, provided in the latest edition of the United States Pharmacopoeia or
the National Formulary, or that violate any provision of the Sherman Food, Drug,

1 and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of
the Health and Safety Code). ...

2 19. Title 16, California Code of Regulations (CCR), section 1707.2 states in part:

3 ...

4 (b) (2) When the patient or agent is not present (including but not limited to a
5 prescription drug that was shipped by mail) a pharmacy shall ensure that the patient
receives written notice:

6 (A) of his or her right to request consultation; and

7 (B) a telephone number from which the patient may obtain oral consultation from a
8 pharmacist who has ready access to the patient's record.

9 ...

10 20. Title 16, CCR, section 1707.5 states in part:

11 ...

12 (d) The pharmacy shall have policies and procedures in place to help patients with
13 limited or no English proficiency understand the information on the label as
14 specified in subdivision (a) in the patient's language. The pharmacy's policies and
15 procedures shall be specified in writing and shall include, at minimum, the selected
16 means to identify the patient's language and to provide interpretive services in the
17 patient's language. The pharmacy shall, at minimum, provide interpretive services
18 in the patient's language, if interpretive services in such language are available,
during all hours that the pharmacy is open, either in person by pharmacy staff or by
19 use of a third-party interpretive service available by telephone at or adjacent to the
20 pharmacy counter.

21 ...

22 21. Title 16, CCR, section 1735.2 states in part:

23 ...

24 (k) Prior to allowing any drug product preparation to be compounded in a
25 pharmacy, the pharmacist-in-charge shall complete a self-assessment for
26 compounding pharmacies developed by the board (Incorporated by reference is
27 "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-
28 Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16,
Division 17, of the California Code of Regulations. That form contains a first
section applicable to all compounding, and a second section applicable to sterile
injectable compounding. The first section must be completed by the pharmacist-in-
charge before any compounding is performed in the pharmacy. The second section
must be completed by the pharmacist-in-charge before any sterile compounding is
performed in the pharmacy. The applicable sections of the self-assessment shall
subsequently be completed before July 1 of each odd-numbered year, within 30
days of the start date of a new pharmacist-in-charge or change of location, and
within 30 days of the issuance of a new pharmacy license. The primary purpose of

1 the self-assessment is to promote compliance through self-examination and
education.

2 ...

3 22. Title 16, CCR, section 1793.7, subdivision (c) states, "A pharmacy technician must
4 wear identification clearly identifying him or her as a pharmacy technician."

5 23. Health and Safety Code section 111440 states, "It is unlawful for any person to
6 manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

7 24. Title 21, Code of Federal Regulations (CFR), section 1304.11 states in part:

8 (a) General requirements. Each inventory shall contain a complete and accurate
9 record of all controlled substances on hand on the date the inventory is taken, and
shall be maintained in written, typewritten, or printed form at the registered
10 location. An inventory taken by use of an oral recording device must be promptly
transcribed. Controlled substances shall be deemed to be "on hand" if they are in
11 the possession of or under the control of the registrant, including substances
returned by a customer, ordered by a customer but not yet invoiced, stored in a
12 warehouse on behalf of the registrant, and substances in the possession of
employees of the registrant and intended for distribution as complimentary
13 samples. A separate inventory shall be made for each registered location and each
independent activity registered, except as provided in paragraph (e)(4) of this
14 section. In the event controlled substances in the possession or under the control of
the registrant are stored at a location for which he/she is not registered, the
15 substances shall be included in the inventory of the registered location to which
they are subject to control or to which the person possessing the substance is
16 responsible. The inventory may be taken either as of opening of business or as of
the close of business on the inventory date and it shall be indicated on the
17 inventory.

18 ...

19 25. Title 21, CFR, section 1304.21 states in part:

20 (a) Every registrant required to keep records pursuant to § 1304.03 shall maintain,
21 on a current basis, a complete and accurate record of each substance manufactured,
imported, received, sold, delivered, exported, or otherwise disposed of by him/her,
22 and each inner liner, sealed inner liner, and unused and returned mail-back
package, except that no registrant shall be required to maintain a perpetual
23 inventory.

24 ...

25 COST RECOVERY

26 26. Section 125.3 of the Code states, in pertinent part, that the Board may request the
27 administrative law judge to direct a licentiate found to have committed a violation or violations of
28

1 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
2 enforcement of the case.

3 DRUGS

4 27. The following drugs are designated as dangerous drugs pursuant to Code section
5 4022:

| 6 BRAND NAME | 7 GENERIC NAME | 8 INDICATION FOR USE |
|---------------|--------------------------|-------------------------------------|
| 9 Effexor | 10 venlafaxine | 11 Depression |
| 12 Janumet | 13 sitagliptin/metformin | 14 Diabetes |
| 15 Januvin | 16 sitagliptin | 17 Diabetes |
| 18 Keppra | 19 levetiracetam | 20 Treatment/prevention of seizures |
| 21 Lasix | 22 furosemide | 23 Treatment of excess fluid |
| 24 Niaspan ER | 25 niacin | 26 High cholesterol |
| 27 Remeron | 28 mirtazapine | Treatment of depression |
| Reyataz | atazanavir | HIV treatment |
| Seroquel | quetiapine | Schizophrenia, bipolar disorder |
| Zyprexa | olanzapine | Schizophrenia, bipolar disorder |

14 28. The following drugs are designated as dangerous drugs pursuant to Code section 4022
15 and controlled substances:

| 16 BRAND NAME | 17 GENERIC NAME | 18 CONTROLLED SUBSTANCE PER Health & Safety Code | 19 INDICATION FOR USE |
|---------------|-----------------|--|-------------------------|
| 20 Ativan | 21 lorazepam | 22 § 11057(d)(16) | 23 Treatment of anxiety |
| 24 Restoril | 25 temazepam | 26 § 11057(d)(29) | 27 Treatment of anxiety |
| 28 Xanax | alprazolam | § 11057(d)(1) | Treatment of anxiety |

21 FACTS

22 29. On April 2, 2014, the Board received an anonymous complaint alleging that non-
23 licensed personnel were performing the duties of a pharmacy technician at Respondent Value
24 Care. On or about July 8, 2014, Board inspectors conducted an inspection of Respondent Value
25 Care located at 17662 Irvine Blvd., No. 14, Tustin. PIC Tonnu, Rojas, biller/payroll manager
26 S.R., pharmacy technician A.B. and clerks D.N., G.H., J.D. and N.R. were present during the
27 inspection. The inspectors entered the filling area and observed three pharmacy personnel filling
28 prescriptions. The personnel identified themselves as Pharmacy Technicians E.S., G.S. and

1 J.S.B. Pharmacy Technician G.S. and J.S.B. were not wearing identification badges. J.S.B.
2 advised the Board inspector that she was a pharmacist from the Philippines and was waiting to
3 take her test. When the Board inspector was unable to verify J.S.B.'s pharmacy technician status
4 on the Board's website, J.S.B. advised the Board inspector that she was in the process of
5 obtaining her pharmacy technician license. However, as of July 9, 2016, the Board had not
6 received any application for licensure from J.S.B.

7 30. Inspector M.A. found bubble packs of previously labeled prescriptions in bins located
8 in a room behind the filling area of the pharmacy. The bubble packs were stored on shelves in
9 bins, some marked with letters of the alphabet and some marked as "expired meds." E.S. advised
10 the inspector that the medications in the bins had been returned by various facilities and were to
11 be reused. The only records kept of the bubble-packed medications were the lot number,
12 expiration date, and the NDC number on the strip labels. There initials of the person who filled
13 the bubble packs were not recorded, nor were the initials of the pharmacist who checked the
14 prescriptions.

15 31. The investigators requested the pharmacy's written policies and procedures for
16 Interpretive Services for patients with limited or no English proficiency and for theft or
17 impairment by licensed employees. PIC Tonnu was unable to provide the requested policies and
18 procedures.

19 32. The Board investigator asked PIC Tonnu how the pharmacy provided written notice
20 of the patient's right to request consultation since most of the pharmacy's prescriptions were
21 delivered to the patients in facilities. PIC Tonnu stated the pharmacy was available to provide
22 consultation upon request but was unable to provide documentation that written notice was being
23 given to patients about their right to request consultation, along with a telephone number to obtain
24 an oral consultation from a pharmacist. PIC Tonnu stated no offer to receive consultation was
25 available on the delivery ticket or on any other printed material included with the delivery of the
26 patient's medications.

27 33. While checking the pharmacy for outdated drugs, Inspector M.A. found two
28 medication bottles that felt over full. Inspector M.A. removed the bottles and conducted an

1 inventory of the contents of the bottles with PIC Tonnu. The first was an open manufacturer's
2 bottle labeled Janumet 50/1000mg tablets NDC 0006-057706, 60 count that contained 77 tablets.
3 The other bottle was an open manufacturer's bottle labeled Reyataz 300 mg capsules NDC 0003-
4 03622-12, 30 count, that contained 37 capsules. Inspector M.A. educated PIC Tonnu about
5 potentially misbranded drugs, performed a paper inventory of the misbranded stock and
6 segregated them for reverse distribution.

7 34. During the inspection, PIC Tonnu provided a controlled substance inventory dated
8 December 27, 2012 as the last biennial inventory conducted. The inventory was missing a record
9 of Schedule II controlled substances and failed to state that the inventory was conducted at the
10 open or close of business. Inspector S.P. educated PIC Tonnu about the requirements for the
11 inventory and PIC Tonnu stated she would conduct an inventory as soon as possible.

12 35. Because the Board inspectors were advised that the pharmacy occasionally
13 compounded drug products such as "magic mouth wash," PIC Tonnu was asked to provide the
14 last compounding self-assessment she completed. PIC Tonnu stated she had not completed the
15 first section applicable to all compounding before the pharmacy began compounding. Inspector
16 S.P. educated PIC Tonnu about the requirement to perform a compounding self-assessment and
17 asked PIC Tonnu to provide the completed self-assessment to him after the inspection.

18 36. The Board inspectors obtained certain documents from PIC Tonnu before leaving the
19 pharmacy at the conclusion of inspection. Inspector S.P. requested that PIC Tonnu provide her
20 with the following documents before July 18, 2014: a biennial DEA inventory including CII-V
21 drugs conducted on or after July 8, 2014; page 1 and signature page of completed and signed
22 compounding pharmacy self-assessment; the plan of action to gain compliance with 'offer of
23 consultation' requirement; the pharmacy's policies and procedures for interpretive services and
24 theft/impairment; a example of a pre-packing log; proof that of the two misbranded drugs
25 (Janumet and Reyataz) sent for destruction; and, a plan of action to maintain the security of the
26 drugs as it related to the open door from the ante room/reception area to the pharmacy area.

27 37. On July 17, 2014, Inspectors S.P. and M.A. conducted a second inspection of the
28 pharmacy. The inspectors noticed the pharmacy had discarded many of the bubble packs the

1 inspectors had seen during their inspection on July 8, 2014. However, bubble-packed medications
 2 were found in two rooms in the pharmacy. Kurien informed the inspectors that Room 1 contained
 3 bubble packs of medications for which the insurance claims were reversed and the medications to
 4 be reused.

5 a. The following full packs of medications that were found in Room 1 include:

| Rx Number | Patient | Medication, strength | Date Filled | Quantity |
|-----------|---------|----------------------|-------------|----------|
| 289236-R | L.S. | Fazaclo, 150mg ODT | 3/10/2014 | 30 |
| 299959-R | P.G. | Savella, 25mg | 6/23/2014 | 62 |
| 294580-N | A.O. | Zyprexa 5mg | 12/23/2013 | 18 |
| 299682-R | A.T. | Seroquel 25 mg | 6/28/2014 | 93 |
| 281537-R | S.S. | Fanapt 2mg | 7/29/2013 | 62 |
| 280902-N | M.T. | Wellbutrin XL 300mg | 6/5/2013 | 25 |
| 301686 | G.H. | Seroquel 200mg | 6/28/2014 | 31 |
| 297426-N | R.R. | Seroquel XR 400mg | 2/27/2014 | 31 |
| 306994-N | C.P. | Zyprexa 20mg | 7/1/2014 | 62 |
| 301467 | I.M. | Vimpat 50mg | 7/1/2014 | 62 |
| 294922-R | L.J.S. | Synthroid 175 mcg | 3/5/2014 | 30 |
| 283877-R | T.R. | Fanapt 8 mg | 9/30/2013 | 62 |
| 302024-R | M.B. | Lyrica 50 mg | 6/20/2014 | 62 |
| 294490-R | A.N. | Fanapt 4mg | 3/27/2014 | 60 |
| 268165-R | I.M. | Zyprexa 15 mg | 7/15/2013 | 31 |
| 301810-R | R.M. | Singulair 10 mg | 5/24/2014 | 30 |
| 305783-R | P.S. | Abilify 10 mg | 7/9/2014 | 31 |
| 292726-R | A.C. | Fazaclo ODT 150 mg | 3/26/2014 | 30 |

17 b. The following partial packs of medications that were found in Room 1 include:

| Rx Number | Medication, Strength | Fill Date | Quantity Dispensed | Quantity Punched Out | Patient |
|-----------|----------------------|------------|--------------------|----------------------|---------|
| 292070 | Seroquel XR, 300mg | 7/10/2014 | 62 | 24 | A.R. |
| 288423 | Seroquel, 300mg | 3/26/2014 | 60 | 46 | D.G. |
| 291612 | Niaspan ER, 1000mg | 11/12/2013 | 31 | 5 | R.A. |
| 293778 | Januvia, 100mg | 12/10/2013 | 31 | 9 | K.M. |
| 270172 | Zyprexa, 7.5mg | 2/28/2013 | 31 | 15 | J.P. |
| 276011 | Effexor XR, 150mg | 6/30/2013 | 31 | 2 | A.F. |

26 38. Kurien informed the inspectors that Room 2 contained loose medications in plastic
 27 bags as well as medications in bubble packs in alphabetically labeled bins. The inspectors were
 28 advised by Kurien that the medications in Room 2 were reversed and were waiting to be sent for

1 destruction. According to Kurien, itemized records of disposition of medication that had been
 2 sent for destruction were not available.

3 a. The following full packs of medications that were found in Room 2 include:

| Rx Number | Date Filled | Medication, Strength | Quantity Filled |
|-----------|-------------|----------------------|-----------------|
| 294990-R | 4/16/2014 | clonazepam, 0.5mg | 62 x 2 |
| 302693-N | 5/1/2014 | clonazepam, 0.5mg | 15 |
| 302104-R | 6/6/2014 | clonazepam, 0.5mg | 62 x 2 |
| 295373-R | 3/27/2014 | clonazepam, 0.5mg | 90 x 2 |
| 291526-N | 11/7/2013 | clonazepam, 0.5mg | 93 x 3 |
| 300379 | 4/16/2014 | clonazepam, 0.5mg | 31 |
| 293276-R | 4/10/2014 | clonazepam, 0.5mg | 31 |
| 299275-R | 4/27/2014 | clonazepam, 0.5mg | 93 x 3 |
| 305002-N | 5/21/2014 | clonazepam, 1mg | 30 x 2 |
| 293311-N | 12/2/2013 | flurazepam, 15mg | 31 |
| 307740-N | 7/8/2014 | lorazepam, 1mg | 30 |
| 300064-N | 4/1/2014 | clonazepam, 0.5mg | 31 |
| 296109-R | 4/22/2014 | alprazolam, 0.25mg | 93 x 3 |

12 b. The following partial packs of medications that were found in Room 2 include:

| Rx Number | Date Filled | Medication, strength | Quantity Filled | Quantity Remaining |
|-----------|-------------|----------------------|-----------------|--------------------|
| 297209-R | 5/11/2014 | lorazepam, 1mg | 30 x 3 | 7 x 3 |
| 299200-R | 5/9/2014 | temazepam, 15mg | 30 | 9 |
| 304021-N | 5/8/2014 | lorazepam, 0.5mg | 10.5 | 10 |

16 c. The following partial packs of controlled substances that were found in Room 2
 17 include:

| Rx Number | Medication, Strength | Fill Date | Quantity Dispensed | Quantity Punched Out | Name of Patient |
|-----------|----------------------|-----------|--------------------|----------------------|-----------------|
| 297209-R | lorazepam 1mg | 5/11/2014 | 30x3 | 23x3 | A.T. |
| 299200-R | temazepam 15mg | 5/9/2014 | 30 | 21 | A.K. |
| 304021-N | lorazepam 0.5mg | 5/8/2014 | 10.5 | 0.5 | C.G. |

22 39. During the July, 2014, inspection, Inspector M.A. observed bubble-packed
 23 medications requiring protection from light that were improperly stored, which include the
 24 following:

| RX number | Medication |
|-----------|---------------------|
| 296408 | mirtazapine 15mg |
| 279026 | risperidone 3mg |
| 301587 | risperidone 4mg |
| 301586 | risperidone 3mg |
| 305133 | levitiracetam 250mg |
| 290714 | furosemide 40mg |

| | |
|--------|------------------|
| 291190 | mirtazapine 30mg |
| 302009 | risperidone 1mg |

40. The pharmacy and PIC Tonnu were unable to provide proper records of acquisition or disposition for the 12 bubble-packed dangerous drugs found during the July 8, 2014, and July 17, 2014, inspections. The dangerous drugs listed below were in medication cards with partially punched out bubbles. A review of the documentation provided by PIC Tonnu include the following:

| Rx Number | Medication, Strength | Fill Date | Quantity Dispensed | Quantity Punched Out | Pharmacy Response to Acquisition Record Request | Pharmacy Response to Disposition Record Request |
|-----------|----------------------|---------------|--------------------|----------------------|---|--|
| 279026 | risperidone, 3mg | 1/5/2014 | 31 | 6 | Record incomplete; inaccurate quantity; "extra card" | Delivery signature log signed 1/21/2014 |
| 301587 | risperidone, 4mg | 5/21/2014 | 31 | 5 | Record incomplete; inaccurate quantity; "extra card" | Delivery signature log signed 5/13/2014 |
| 301586 | risperidone, 3mg | 5/21/2014 | 31 | 6 | Record incomplete; inaccurate quantity; "extra card" | Delivery signature log signed 5/13/2014 |
| 302009N | risperidone 1mg | Original fill | 31 | 9 | Record has inaccurate quantity; "Duplicate" | Delivery signature log for Rx date of 6/6/2014 |
| 292070 | Seroquel XR, 300mg | 7/10/2014 | 62 | 24 | Record incomplete; inaccurate quantity | Delivery signature log for Rx date of 7/10/2014 |
| 288423 | Seroquel, 300mg | 3/26/2014 | 60 | 46 | Record incomplete; inaccurate quantity | Delivery report, unsigned, for Rx date of 3/26/2014 |
| 291612 | Niaspan ER, 1000mg | 11/12/2013 | 31 | 5 | "Perform Rx covered generics. The generic as dispensed to the patient and the extra packaged card with the brand was kept in the pharmacy"; (does not explain the 5 punched out | Daily delivery log dated 12/5/2013 for generic medication with a fill date of 11/12/2013 |
| 293778 | Januvia, 100mg | 12/10/2013 | 31 | 9 | Rx was reversed. No acquisition record provided and no explanation for the 9 punched out tablets. | Delivery signature log signed 12/21/2013 |

| | | | | | | | |
|----|--------|----------------------|-----------|--------|--------|--|---|
| 1 | 270172 | Zyprexa, 7.5mg | 2/28/2013 | 31 | 15 | Attached medication sheet shows medication was discontinued 3/15/2013; no record of acquisition provided | Delivery signature log dated 2/28/2013 and signed |
| 2 | | | | | | | |
| 3 | | | | | | | |
| 4 | 276011 | Effexor XR, 150mg | 6/30/2013 | 31 | 2 | "Health Net only covers generics. The generic was dispensed to the patient and the extra packaged card with the brand was kept at the pharmacy." (does not explain the 2 punched out) | Daily delivery log dated 7/1/2013 for generic medication with fill date of 7/1/2013 |
| 5 | | | | | | | |
| 6 | | | | | | | |
| 7 | | | | | | | |
| 8 | | | | | | | |
| 9 | 297209 | lorazepam, 1mg | 5/11/2014 | 30 x 3 | 23 x 3 | "As you can see on attached signed medsheet the patient did take the medication and the duplicate cards were never sent out." (does not explain the 23 x 3 punched out; no record of acquisition provided) | Delivery signature log signed 5/12/2014 |
| 10 | | | | | | | |
| 11 | | | | | | | |
| 12 | | | | | | | |
| 13 | | | | | | | |
| 14 | | | | | | | |
| 15 | 299200 | temazepam,1 5mg | 5/9/2014 | 30 | 21 | "As you can see on attached signed medsheet the patient did take the medication and the duplicate cards were never sent out." (does not explain the 21 punched out; no record of acquisition provided) | Delivery signature log with pickup date of 5/23/2014 |
| 16 | | | | | | | |
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FIRST CAUSE FOR DISCIPLINE

As to All Respondents

(Employment of Unlicensed Pharmacy Technician)

41. Respondents Value Care Pharmacy, Tonnu, Rojas and Kurien, are subject to disciplinary action under Code section 4115(d) and (e) in that on July 8, 2014, Respondents employed J.S.B. as a pharmacy technician when J.S.B. was not licensed by the Board as a pharmacy technician, as more fully set forth in paragraphs 29-40 above and incorporated by this reference as though set forth in full herein.

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1 **SECOND CAUSE FOR DISCIPLINE**

2 **As to All Respondents**

3 **(Failure to Ensure Compliance with Regulations**

4 **Regarding Employment of Pharmacy Technicians)**

5 42. Respondents Value Care Pharmacy, Tonnu, Rojas and Kurien, are subject to
6 disciplinary action under Code section 4301(o) for directly or indirectly, or assisting in or abetting
7 the violation of title 16, CCR, section 1793.7(c), in that Pharmacy Technician G.S. was not
8 wearing any identification clearly identifying him as a Pharmacy Technician during the inspection
9 on July 8, 2014, as more fully set forth in paragraphs 29-40 above and incorporated by this
10 reference as though set forth in full herein.

11 **THIRD CAUSE FOR DISCIPLINE**

12 **As to All Respondents**

13 **(Failure to Comply with Controlled Substance Inventory Requirements)**

14 43. Respondents Value Care Pharmacy, Tonnu, Rojas and Kurien, are subject to
15 disciplinary action under Code section 4301(j) and (o) in conjunction with title 21, CFR, section
16 1304.11(a), for violating laws and regulations governing pharmacy and controlled substances in
17 that Respondents failed to maintain an inventory that contains a complete and accurate record of
18 all controlled substances on hand on the date the inventory is taken, and failed to indicate on the
19 inventory whether the inventory was taken either as of opening of business or as of the close of
20 business on the inventory date.

21 44. During the inspection on July 8, 2014, the inventory dated December 27, 2012, was
22 provided as Respondents' last inventory conducted. The inventory was missing a record of
23 Schedule II controlled substances and failed to state whether the inventory was conducted at the
24 open or close of business, as more fully set forth in paragraphs 29-40 above and incorporated by
25 this reference as though set forth in full herein.

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1 **FOURTH CAUSE FOR DISCIPLINE**

2 **As to All Respondents**

3 **(Failure to Complete Self-Assessment for Compounding Pharmacies)**

4 45. Respondents Value Care Pharmacy, Tonnu, Rojas and Kurien, are subject to
5 disciplinary action under Code section 4301(o) for directly or indirectly, or assisting in or abetting
6 the violation of title 16, CCR, section 1735.2(k), in that as of July 8, 2014, the Pharmacist-in-
7 Charge, Tonnu, had not completed the first section of the self-assessment form for compounding,
8 applicable to all compounding pharmacies, before the pharmacy began occasional compounding,
9 as more fully set forth in paragraphs 29-40 above and incorporated by this reference as though set
10 forth in full herein

11 **FIFTH CAUSE FOR DISCIPLINE**

12 **As to All Respondents**

13 **(Written Notice of Right to Request Consultation)**

14 46. Respondents Value Care Pharmacy, Tonnu, Rojas and Kurien, are subject to
15 disciplinary action under Code section 4301(o) for directly or indirectly, or assisting in or abetting
16 the violation of title 16, CCR, section 1707.2(b)(2), in that Respondents failed to ensure that when
17 the patient or patient's agent is not present, the patient receives written notice of his or her right to
18 request consultation and a telephone number from which the patient may obtain oral consultation
19 from a pharmacist who has ready access to the patient's record.

20 47. During the inspection on July 8, 2014, Respondents were not able to provide
21 documentation that written notice was provided to patients of their right to request consultation,
22 along with a telephone number from which a patient may obtain oral consultation from a
23 pharmacist. Neither the prescription delivery ticket nor any other printed material included with
24 the delivery of the patient's medications provided such notification, as more fully set forth in
25 paragraphs 29-40 above and incorporated by this reference as though set forth in full herein.

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1 **SIXTH CAUSE FOR DISCIPLINE**

2 **As to All Respondents**

3 **(Written Policies and Procedures For Addressing Impairment, Theft and Diversion)**

4 48. Respondents Value Care Pharmacy, Tonnu, Rojas and Kurien, are subject to
5 disciplinary action under Code section 4104(b) for failing to have written policies and procedures
6 for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of
7 dangerous drugs, among licensed individuals employed by or with the pharmacy, as more fully set
8 forth in paragraphs 29-40 above and incorporated by this reference as though set forth in full
9 herein.

10 **SEVENTH CAUSE FOR DISCIPLINE**

11 **As to All Respondents**

12 **(Written Policies and Procedures For Interpretive Services)**

13 49. Respondent Value Care Pharmacy is subject to disciplinary action under title 16,
14 CCR, section 1707.5 for failing to have written policies and procedures to help patients with
15 limited or no English proficiency understand the information on the prescription label, as more
16 fully set forth in paragraphs 29-40 above and incorporated by this reference as though set forth in
17 full herein.

18 **EIGHTH CAUSE FOR DISCIPLINE**

19 **As to All Respondents**

20 **(Selling, Delivering, Holding or Offering Misbranded Drugs)**

21 50. Respondent Value Care Pharmacy is subject to disciplinary action under Code section
22 4301, subdivisions (j) and (o), in conjunction with Health and Safety Code section 111440 for
23 manufacturing, selling, delivering, holding, and/or offer for sale in that on July 8, 2014,
24 Respondent had on their pharmacy shelves, an opened manufacturer bottle of Janumet 50/1000mg
25 tablets NDC 0006-0577-61, 60 count containing 77 tablets and an opened manufacturer bottle of
26 Reyataz 300mg capsules NDC 0003-3622-12, 30 count, containing 37 capsules, as more fully set
27 forth in paragraphs 29-40 above and incorporated by this reference as though set forth in full
28 herein.

1 **NINTH CAUSE FOR DISCIPLINE**

2 **As to All Respondents**

3 **(Lacking Records of Acquisition or Disposition)**

4 51. Respondents Value Care Pharmacy, Tonnu, Rojas and Kurien, are subject to
5 disciplinary action under Code sections 4081(a) and 4105(a) for failing to provide proper records
6 of acquisition or disposition for the drugs listed in paragraph 40 and as more fully set forth in
7 paragraphs 29-40 above and incorporated by this reference as though set forth herein.

8 **TENTH CAUSE FOR DISCIPLINE**

9 **As to All Respondents**

10 **(Lacking Records of Acquisition for Controlled Substances)**

11 52. Respondents Value Care Pharmacy, Tonnu, Rojas and Kurien, are subject to
12 disciplinary action under Code section 4301(j) in conjunction with title 21, CFR, section
13 1304.21(a) in that on July 8, 2014 and July 17, 2017, Respondent was unable to provide proper
14 records of acquisition for two prescriptions for controlled substances with some punched out
15 bubbles as set forth below and in paragraphs 29-40 above and incorporated by this reference as
16 though set forth herein:

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| Rx Number | Medication, Strength | Fill Date | Quantity Dispensed | Quantity Punched Out | Pharmacy Response to Acquisition Record Request |
|-----------|----------------------|-----------|--------------------|----------------------|--|
| 297209 | lorazepam, 1mg | 5/11/2014 | 30 x 3 | 23 x 3 | "As you can see on attached signed medsheet the patient did take the medication and the duplicate cards were never sent out." (Does not explain 23 x 3 punched out bubbles). |
| 299200 | temazepam, 15mg | 5/9/2014 | 30 | 21 | "As you can see on attached signed medsheet the patient did take the medication and the duplicate cards were never sent out." (Does not explain |

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OTHER MATTERS

53. Pursuant to Section 4307, if Pharmacy Permit Numbers PHY 44873 and/or Pharmacy Permit Number PHY 54247 issued to Rely On Pharmacy, Inc., dba Value Care Pharmacy is suspended, revoked or placed on probation, and Respondent Kurien, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 44873 was revoked, suspended, or placed on probation, Respondent Kurien shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

54. Pursuant to Section 4307, if Pharmacist License Number RPH 45201 issued to Respondent Kurien is suspended or revoked, Respondent Kurein shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

55. Pursuant to Section 4307, if Pharmacy Permit Number PHY 44873 and/or Pharmacy Permit Number PHY 54247 issued to Rely On Pharmacy, Inc., dba Value Care Pharmacy is suspended, revoked or placed on probation, and Respondent Tonnu, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 44873 was revoked, suspended, or placed on probation, Respondent Tonnu shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

56. Pursuant to Section 4307, if Pharmacist License Number RPH 51367 issued to Respondent Tonnu is suspended or revoked, Respondent Tonnu shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

57. Pursuant to Section 4307, if Pharmacy Permit Number PHY 44873 and/or Pharmacy Permit Number PHY 54247 issued to Rely On Pharmacy, Inc., dba Value Care Pharmacy is suspended, revoked or placed on probation, and Respondent Rojas, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or

1 knowingly participated in any conduct for which Pharmacy Permit Number PHY 44873 was
2 revoked, suspended, or placed on probation, Respondent Rojas shall be prohibited from serving as
3 a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of
4 the Board.

5 58. Pursuant to Section 4307, if Pharmacist Technician License Number TCH 4571 to
6 Respondent Rojas is suspended or revoked, Respondent Rojas shall be prohibited from serving as
7 a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

8 PRAYER

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

11 1. Revoking or suspending Pharmacy Permit Number PHY 44873 issued to Rely on
12 Pharmacy, Inc., dba Value Care Pharmacy;

13 2. Revoking or suspending Pharmacy Permit Number PHY 54247 issued to Rely on
14 Pharmacy, Inc., dba Value Care Pharmacy;

15 3. Revoking or suspending Pharmacist License Number RPH 45201 issued to Thomas
16 Kurien;

17 4. Prohibiting Thomas Kurien from serving as a manager, administrator, owner,
18 member, officer, director, associate, or partner of a licensee of the Board;

19 5. Revoking or suspending Pharmacist License Number RPH 51367 issued to Annie
20 Tonnu;

21 6. Prohibiting Annie Tonnu from serving as a manager, administrator, owner, member,
22 officer, director, associate, or partner of a licensee of the Board;

23 7. Revoking or suspending Pharmacy Technician License Number TCH 4571 issued to
24 Daniel Rojas;

25 8. Prohibiting Daniel Rojas from serving as a manager, administrator, owner, member,
26 officer, director, associate, or partner of a licensee of the Board;

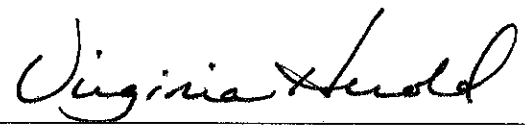
27 9. Ordering Rely on Pharmacy, Inc., dba Value Care Pharmacy, Thomas Kurien, Annie
28 Tonnu and Daniel Rojas, jointly and severally, to pay the Board of Pharmacy the reasonable costs

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of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 6/30/17



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

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