XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
DAVID E. BRICE
Deputy Attorney General
State Bar No. 269443
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 324-8010
Facsimile: (916) 327-8643
E-mail: David.Brice@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **ALLWELL PHARMACY AND MEDICAL SUPPLIES, LLC; CLETUS UCHE DURU, MEMBER AND PHARMACIST-IN-CHARGE** **5611 Stockton Blvd.** **Sacramento, CA 95824** **Pharmacy Permit No. PHY 50426,** **and** **CLETUS UCHE DURU** **5611 Stockton Blvd.** **Sacramento, CA 95824** **Pharmacist License No. RPH 46402** Respondents.	Case No. 6012 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about November 1, 2010, the Board of Pharmacy issued Pharmacy Permit Number PHY 50426 to Allwell Pharmacy and Medical Supplies, LLC (Respondent Allwell) with

Cletus Uche Duru as a Member and as Pharmacist-In-Charge (PIC). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2017, unless renewed.

3. On or about August 16, 1993, the Board of Pharmacy issued Pharmacist License Number RPH 46402 to Cletus Uche Duru (Respondent Duru). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2017, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 4300 of the Code states, in pertinent part:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the 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 any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

7. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or

who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

(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.

STATUTORY PROVISIONS

8. Section 4301 of the Code states, in pertinent part:

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.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the

customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

...

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

...

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

9. 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.

10. Section 4113 of the Code states, in pertinent part:

(a) Every pharmacy shall designate a pharmacist-in-charge ...

...

(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.

11. Section 4115 of the Code states, in pertinent part:

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

...

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

12. Section 4306.5 of the Code states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

13. Section 4332 of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

HEALTH AND SAFETY CODE

14. Section 11153 of the Health and Safety Code states, in pertinent part:

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

///

15. Section 11164 of the Health and Safety Code states, in pertinent part:

[N]o person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, 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 meet the following requirements:

(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 ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill 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.

FEDERAL REGULATION

16. Section 1304.11 of title 21 of the Code of Federal Regulations (21 CFR 1304.11) states, in pertinent part:

(a) General requirements. Each inventory shall contain a complete and accurate 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 location. … 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 inventory.

…

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

CALIFORNIA REGULATIONS

17. Section 1707.5 of title 16 of the California Code of Regulations (16 CCR 1707.5) states, in pertinent part:

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient.

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

18. 16 CCR 1711 states, in pertinent part:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

...

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

...

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

19. 16 CCR 1715.6 states: "The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths."

20. 16 CCR 1718 states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

21. 16 CCR 1761 states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not 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 legitimate medical purpose.

22. 16 CCR 1793.2 states:

"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:

(a) removing the drug or drugs from stock;

(b) counting, pouring, or mixing pharmaceuticals;

(c) placing the product into a container;

(d) affixing the label or labels to the container;

(e) packaging and repackaging.

CONTROLLED SUBSTANCES

23. Alprazolam is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(1), and is sold under the brand name Xanax.

24. Clonazepam is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(7), and is sold under the brand name Klonopin.

///

25. Diazepam is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(9), and is sold under the brand name Valium.

26. Hydrocodone/APAP 10/325 is a Schedule III controlled substance as designated by Health and Safety Code section 11056(e)(5), and is sold under the brand names Norco or Lortab.

27. Methadone is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (c)(14).

28. Oxycodone is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(M).

29. Promethazine/codeine is a Schedule V controlled substance as designated by Health and Safety Code section 11058, subdivision (c)(1) and is sold under the brand name Phenergan with Codeine Syrup.

COST RECOVERY

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

CAUSES FOR DISCIPLINE

Allwell Pharmacy and Medical Supplies, LLC (Allwell)

FIRST CAUSE FOR DISCIPLINE

(Unlicensed Activity)

31. Respondent Allwell is subject to disciplinary action under Code section 4115, subdivisions (a) and (e) and 16 CCR 1793.2, by and through Code section 4301(o), in that Respondent allowed unlicensed staff to perform the duties of a pharmacy technician. The circumstances are as follows:

32. On or about May 5, 2016 and during a subsequent investigation, Respondent had an unlicensed pharmacy clerk perform the duties of a pharmacy technician, including opening a stock prescription bottle, pouring the drug onto a counting tray, counting the drug to be dispensed

///

to a patient, placing the counted drug into a container, and sealing the container. This was confirmed to be a standard workflow practice at Respondent pharmacy.

SECOND CAUSE FOR DISCIPLINE

(Reporting Drug Loss)

33. Respondent Allwell is subject to disciplinary action under 16 CCR 1715.6, by and through Code section 4301(o), in that Respondent failed to report the loss of controlled substances, including their amounts and strengths, to the Board within thirty (30) days. The circumstances are as follows:

34. On or about May 5, 2016, and during a subsequent investigation, it was found that in 2012, six to eight pint-size bottles of promethazine/codeine, a Schedule V controlled substance, were stolen from Respondent during business hours. Respondent was aware of the theft and did not report the loss to the Board.

THIRD CAUSE FOR DISCIPLINE

(Failure to Participate in Quality Assurance Program)

35. Respondent Allwell is subject to disciplinary action under 16 CCR 1711, by and through Code section 4301(o), in that Respondent failed to participate in an established quality assurance program. The circumstances are as follows:

36. On or about May 5, 2016, and during a subsequent investigation, it was found that Respondent pharmacy made a medication error on or about August 18, 2015. Prescription number 740903 was dispensed in error to a patient for the wrong package of Apidra, a dangerous drug. The prescription was returned to the pharmacy by the patient when the error was discovered. Respondent pharmacy did not document an incident report of the error, as required by the Quality Assurance Policy. It was also found that other medication errors had occurred within the past year and no documentation of the errors was completed and kept on file so as to have complete details, conduct a review, and prevent a recurrence of the error, as required by the policy.

///

///

FOURTH CAUSE FOR DISCIPLINE

(Requirements for Patient-Centered Labels for Prescriptions)

37. Respondent Allwell is subject to disciplinary action under 16 CCR 1707.5, subdivision (a), by and through Code section 4301(o), in that Respondent failed to comply with the requirements for patient-centered labels on drug containers. The circumstances are as follows:

38. On or about May 5, 2016, and during a subsequent investigation, it was found that Respondent pharmacy labeled prescriptions in a format with the name of the drug and strength of the drug listed after the directions for use of the drug, in violation of the required order.

FIFTH CAUSE FOR DISCIPLINE

(Biennial Inventory and Record Requirements)

39. Respondent Allwell is subject to disciplinary action under Code section 4081, 16 CCR 1718, and 21 CFR 1304.11, by and through Code section 4301(o), in that Respondent failed to comply with the requirements for maintaining an inventory of controlled substances and completing a biennial inventory. The circumstances are as follows:

40. On or about May 5, 2016, and during a subsequent investigation, it was found that Respondent pharmacy had a controlled substance inventory on file which indicated it was printed on November 5, 2014 without an indication of the completion date or if the inventory was completed as of opening or close of business. Respondent pharmacy also had a controlled substance inventory on file dated May/June 2015. There was no indication of an exact date completed or if the inventory was completed as of opening or close of business. After a controlled substance inventory was requested from Respondent pharmacy, a controlled substance inventory was provided which was dated May 8, 2016, a Sunday when the pharmacy was closed. The inventory did not have any entries for the following controlled substances: hydrocodone/APAP 10/325; methadone 10 mg; oxycodone 30 mg; and oxycodone APAP 10/325. Respondent pharmacy's records indicated that these controlled substances were regularly dispensed. Thus, this was not a complete current inventory of all drug stocks on hand. Respondent did not complete a biennial inventory every two years and have the inventory on file.

SIXTH CAUSE FOR DISCIPLINE

(Requirements for Controlled Substance Prescriptions)

41. Respondent Allwell is subject to disciplinary action under Health and Safety Code section 11164, by and through Code section 4301(o), in that Respondent pharmacy dispensed controlled substances using prescription forms that were missing required features. The circumstances are as follows:

42. On or about May 5, 2016, and during a subsequent investigation, it was found that Respondent pharmacy dispensed controlled substance prescriptions for alprazolam 2 mg and hydrocodone/APAP 10/325 mg on February 5, 2015, and alprazolam 2 mg on February 19, 2015, pursuant to prescription forms that were missing the following required features: 1. Watermark printed on back of prescription blank stating "California Security Prescription"; 2. Identifying number assigned to the approved security printer by the Department of Justice; 3. The lot number printed on the form. Furthermore, between May 10, 2013, and February 21, 2014, Respondent pharmacy dispensed controlled substances pursuant to at least thirty (30) prescriptions from Sen Jone, MD, that were missing the following required features: 1. Identifying number assigned to the approved security printer by the Department of Justice; 2. The lot number printed on the form.

SEVENTH CAUSE FOR DISCIPLINE

(Corresponding Responsibility for Legitimacy of Prescription)

43. Respondent Allwell is subject to disciplinary action under Health and Safety Code section 11153 and 16 CCR 1761, by and through Code section 4301(o), in that Respondent pharmacy failed to fulfill its corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances. The circumstances are as follows:

44. On or about May 5, 2016, and during a subsequent investigation which reviewed dispensing data and records from April 1, 2013, to May 5, 2016, it was found that Respondent pharmacy dispensed excessive controlled substances prescriptions with irregularities and red flags of abuse without ensuring the prescriptions were issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. Respondent pharmacy dispensed controlled substances after ignoring, or not being aware of, objective factors

which were irregular from medically legitimate prescriptions. The objective factors of illegitimacy, irregularity, and abuse included but were not limited to:

a. The invalid nature of prescription documents which did not have required features, were fraudulent, or not issued in the usual course of professional practice.

b. Unusually high doses of opioids for opioid naïve patients.

c. Doctor prescribing trends seemingly inconsistent with the primary area of practice for a surgeon who prescribed a high percentage of promethazine/codeine prescriptions on invalid controlled substance forms.

d. Unusually high cash payment profiles from patients obtaining controlled substances with red flags of abuse, such as out-of-the-area prescriber, invalid forms, high initial doses of opioids, and no previous history with the pharmacy.

e. Patients presenting prescriptions from a doctor whose office was over 160 miles from the pharmacy.

f. Many patients receiving the same or similar controlled substances, or combinations of controlled substances, from a doctor whose office was over 160 miles from the pharmacy.[1] On many occasions, the pharmacy dispensed the same combination of controlled substances written by the same prescriber to different patients on the same day, sometimes within minutes of one another.

g. Near uniformity in prescribing trends of controlled substances for a doctor whose office was over 160 miles from the pharmacy.

h. Many patients receiving the highest table strength of controlled substances with no upward titration from a lower dose for prescriptions from a doctor whose office was over 160 miles from the pharmacy, e.g. highest tablet strength of oxycodone, methadone, alprazolam, diazepam, and clonazepam.

i. Many controlled substance prescriptions dispensed from doctors whose licenses became surrendered, revoked, or put on probation.

[1] In three years, Respondent dispensed 653 prescriptions for controlled substances from this doctor, more than any other pharmacy; of those prescriptions, 90.5% were paid in cash.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

45. Respondent Allwell is subject to disciplinary action under Code section 4301, subdivisions (a), (d), (j) and (o), in that Respondent pharmacy committed unprofessional conduct by operating in a grossly negligent manner, violating laws and regulations governing the practice of pharmacy, violating laws and regulations regulating controlled substances, and clearly excessive furnishing of controlled substances without the exercise of its corresponding responsibility to only dispense medically legitimate prescriptions. Respondent pharmacy's conduct constituted gross negligence by operating in violation of the laws and regulations intended to ensure the safe practice of pharmacy and the safe distribution of controlled substances. Respondent pharmacy operated in a manner that was a gross deviation from the standard of safe pharmacy practice, and which could cause harm to patients or other persons. The circumstances are set forth in paragraphs 32, 34, 36, 38, 40, 42, and 44 and its subparts, above.

Cletus Uche Duru

46. Respondent Cletus Uche Duru has been the designated Pharmacist-In-Charge for Allwell Pharmacy and Medical Supplies, LLC under Code section 4113(a) since November 1, 2010. As pharmacist-in-charge for Allwell, Respondent Duru was responsible for Allwell's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy under Code section 4113(c).

NINTH CAUSE FOR DISCIPLINE

(Unlicensed Activity)

47. Respondent Duru is subject to disciplinary action under Code section 4115, subdivisions (a) and (e) and 16 CCR 1793.2, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, allowed unlicensed staff to perform the duties of a pharmacy technician. The circumstances are set forth in paragraph 32 above.

///

///

///

TENTH CAUSE FOR DISCIPLINE

(Reporting Drug Loss)

48. Respondent Duru is subject to disciplinary action under 16 CCR 1715.6, by and through Code section 4301(o), in that that he, as pharmacist-in-charge for Allwell, failed to report the loss of controlled substances, including their amounts and strengths, to the Board within thirty (30) days. The circumstances are set forth in paragraph 34 above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Participate in Quality Assurance Program)

49. Respondent Duru is subject to disciplinary action under 16 CCR 1711, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, failed to participate in an established quality assurance program. The circumstances are set forth in paragraph 36 above.

TWELFTH CAUSE FOR DISCIPLINE

(Requirements for Patient-Centered Labels for Prescriptions)

50. Respondent Duru is subject to disciplinary action under 16 CCR 1707.5, subdivision (a), by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, failed to comply with the requirements for patient-centered labels on drug containers. The circumstances are set forth in paragraph 38 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Biennial Inventory and Record Requirements)

51. Respondent Duru is subject to disciplinary action under Code section 4081, 16 CCR 1718, and 21 CFR 1304.11, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, failed to comply with the requirements for maintaining an inventory of controlled substances and completing a biennial inventory. The circumstances are set forth in paragraph 40 above.

///

///

///

FOURTEENTH CAUSE FOR DISCIPLINE

(Requirements for Controlled Substance Prescriptions)

52. Respondent Duru is subject to disciplinary action under Health and Safety Code section 11164, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, dispensed controlled substances using prescription forms that were missing required features. The circumstances are set forth in paragraph 42 above.

FIFTEENTH CAUSE FOR DISCIPLINE

(Corresponding Responsibility for Legitimacy of Prescription)

53. Respondent Duru is subject to disciplinary action under Health and Safety Code section 11153 and 16 CCR 1761, by and through Code section 4301(o), in that he, as pharmacist-in-charge for Allwell, failed to fulfill his corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances. The circumstances are set forth in paragraph 44, and its subparts, above

SIXTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

54. Respondent Duru is subject to disciplinary action under Code section 4301, subdivisions (a), (d), (j) and (o), in that he, as pharmacist-in-charge for Allwell, committed unprofessional conduct by operating in a grossly negligent manner, violating laws and regulations governing the practice of pharmacy, violating laws and regulations regulating controlled substances, and clearly excessive furnishing of controlled substances without the exercise of its corresponding responsibility to only dispense medically legitimate prescriptions. Respondent Duru's conduct constituted gross negligence by operating in violation of the laws and regulations intended to ensure the safe practice of pharmacy and the safe distribution of controlled substances. Respondent Duru acted in a manner that was a gross deviation from the standard of safe pharmacy practice, and which could cause harm to patients or other persons. The circumstances are set forth in paragraphs 32, 34, 36, 38, 40, 42, and 44 and its subparts, above.

///

///

OTHER MATTERS

55. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50426 issued to Allwell Pharmacy and Medical Supplies LLC, Allwell Pharmacy and Medical Supplies LLC shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50426 is placed on probation or until Pharmacy Permit Number PHY 50426 is reinstated if it is revoked.

56. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50426 issued to Allwell Pharmacy and Medical Supplies LLC, while Cletus Uche Duru has been a member and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Cletus Uche Duru shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50426 is placed on probation or until Pharmacy Permit Number PHY 50426 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 50426, issued to Allwell Pharmacy and Medical Supplies LLC;

2. Revoking or suspending Pharmacist License Number RPH 46402, issued to Cletus Uche Duru;

3. Prohibiting Allwell Pharmacy and Medical Supplies LLC from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50426 is placed on probation or until Pharmacy Permit Number PHY 50426 is reinstated if Pharmacy Permit Number 50426 issued to Allwell Pharmacy and Medical Supplies LLC is revoked;

4. Prohibiting Cletus Uche Duru from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit

Number PHY 50426 is placed on probation or until Pharmacy Permit Number PHY 50426 is reinstated if Pharmacy Permit Number 50426 issued to Allwell Pharmacy and Medical Supplies LLC is revoked;

5. Ordering Allwell Pharmacy and Medical Supplies LLC and Cletus Uche Duru to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 3/18/17

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

SA2016104435
12621459.docx