1	KAMALA D. HARRIS	
2	Attorney General of California FRANK H. PACOE	
3	Supervising Deputy Attorney General JONATHAN D. COOPER	
4	Deputy Attorney General State Bar No. 141461	
	455 Golden Gate Avenue, Suite 11000	
5	San Francisco, CA 94102-7004 Telephone: (415) 703-1404	
6	Facsimile: (415) 703-5480 Attorneys for Complainant	
7	BEFORE THE	
8	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
9	STATE OF CALIFORNIA	
10]
11	In the Matter of the Accusation Against:	Case No. 5904
12	GETWELL PHARMACY & MEDICAL SUPPLY	
13	699 E. 14 th Street San Leandro, CA 94577	ACCUSATION
14	Pharmacy Permit No. PHY 50159	
15	And	
16	MICHAEL CHIKAODINAKA	
17	ACHOLONU P.O. Box 2013	
18	San Leandro, CA 94577	
19	Original Permit No. RPH 45757	·
20	Respondent.	
21	Complainant alleges:	
22	<u>PARTIES</u>	
23	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity	
24	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.	
25	2. On or about September 14, 1992, the Board of Pharmacy issued Original Permit	
26	Number RPH 45757 to Michael Chikaodinaka Acholonu (hereinafter "Respondent Acholonu").	
27	The Original Permit was in full force and effect at all times pertinent to this Accusation and will	
28	expire on September 30, 2018, unless renewed.	
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On or about December 17, 2009, the Board of Pharmacy issued Pharmacy Permit No. 3. PHY 50159 to Getwell Pharmacy & Medical Supply Corp., Michael Chikaodinak Acholonu, President, Owner, Pharmacist-in-Charge (hereinafter "Respondent Getwell Pharmacy"). The License was canceled on February 18, 2015. **JURISDICTION** 4. 5.

- This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.
- Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].
- 6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.
- 7. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, 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.

STATUTORY AND REGULATORY PROVISIONS

Business and Professions Code:

- Section 4059 of the Code, in pertinent part, prohibits furnishing of any dangerous 8. drug or dangerous device except upon the prescription of an authorized prescriber.
 - Section 4081 of the Code states, in pertinent part: 9.
- (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 foodanimal 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 a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.
- 10. Section **4105** of the Code requires, in pertinent part, that unless a waiver is granted by the board, all records and other documentation of the acquisition and disposition of dangerous drugs and devices by any entity licensed by the board be retained on the licensed premises, in a readily retrievable form, for three years from the date of making.
 - 11. Section 4113(c) of the Code states:

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.

12. 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:

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

13. 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.
 - 14. 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.
 - 15. 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.

California Code of Regulations:

16. California Code of Regulations, title 16, section 1707.3 states:

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

17. California Code of Regulations, title 16, section 1715 states:

- (a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
- (b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
 - (1) A new pharmacy permit has been issued, or
- (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
 - (3) There is a change in the licensed location of a pharmacy to a new address.
- (c) The components of this assessment shall be on Form 17M-13 (Rev. 10/14) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on Form 17M-14 (Rev. 10/14) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.
- (d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.
 - 18. California Code of Regulations, title 16, section 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.

- 19. California Code of Regulations, title 16, section 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.

Controlled Substances/Dangerous Drugs:

Section **4021** of the Code provides that a "controlled substance" means any substance listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

20. Section 4022 of the Code states, in pertinent part:

"Dangerous drug: or "dangerous device" means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

- (21.a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import. . . .
- (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.
 - 22. California Health and Safety Code section 11153 states:
- (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.
- (b) Any person who knowingly violates this section shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both that fine and imprisonment.

- (c) No provision of the amendments to this section enacted during the second year of the 1981-82 Regular Session shall be construed as expanding the scope of practice of a pharmacist.
- 23. Promethazine with Codeine Syrup (PCS) is a controlled substance pursuant to Health and Safety Code section 11058 and a dangerous drug pursuant to Business and Professions Code section 4022.
- 24. Norco, or Hydrocodone with Acetaminophen, is a controlled substance pursuant to Health and Safety Code section 11056 and a dangerous drug pursuant to Business and Professions Code section 4022.
- 25. **Soma**, or **Carisoprodol**, is a controlled substance pursuant to title 21 C.F.R. section 1308.14(c)(6)¹ and a dangerous drug pursuant to Business and Professions Code section 4022.

COST RECOVERY

26. Section 125.3 of the Code provides, 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.

FACTUAL SUMMARY

Excessive Furnishing:

- 27. Between July, 2011 and July, 2014, Respondents consistently dispensed controlled substances, which substances had a high potential for abuse, to customers despite the existence of multiple indications that the prescriptions at issue should not be filled. In filling the prescriptions, Respondents ignored significant indications of possible drug abuse including, but not limited to:
 - 1. The fact that the vast majority of the prescriptions, numbering over 16,000, were written by two practitioners.
 - The fact that an unusually high percentage of the customers paid cash for these prescription.
 - 3. The fact that the prescriptions called for excessive amounts of Promethazine with codeine,

¹ Effective January 11, 2012.

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- a medication designed for temporary use.
- 4. The fact that the prescriptions manifested monotonous, non-diverse prescribing practices among different patients involving Promethazine with codeine, Norco and Soma.
- 5. The fact that the prescriptions called for consistently high doses of narcotic without tapering up from lower doses.
- 6. The fact that multiple prescriptions were written, near in time, for numerous individuals at the same address or addresses and/or individuals who shared surnames.
- 7. The fact that many of the individuals lived far away from the pharmacy.
- 8. The fact that the customers often sought, and were provided with, refills earlier than necessary.
- 9. The fact that the prescriptions were, in many cases, inconsistent with applicable standards for geriatric patients.
- 28. During this time period, Respondents failed to appropriately review patients' medication therapy with readily available tools such as Patient Activity Reports, Respondents' own records and consideration of what are considered in the industry to be red flags. As a result, patients were furnished with early and/or excessive amounts of controlled substances, and patients involved in obvious doctor and pharmacy shopping were furnished controlled substances. As a result of these failures, and those set forth above in paragraph, Respondents filled prescriptions which were not for legitimate medical purposes as that term is used in California Health and Safety Code section 11153, in that the prescriptions were for addicts or habitual users.

July 9, 2014 Inspection:

29. On or about July 9, 2014, Board of Pharmacy inspectors conducted an audit of Respondents' records. The records at issue were those pertaining to August 27, 2012 through July 9, 2014. The audit revealed that Respondents failed to account for 379,473 ml of promethazine with codeine, 113,999 tablets of Norco and 40,257 tablets of carisoprodol.

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FIRST CAUSE FOR DISCIPLINE

(Excessive Furnishing)

30. Respondents are each and severally subject to discipline under Code sections 4113(c) and 4301, subsections (d), (j) and (o), and under California Code of Regulations, title 16, section 1761, in that they engaged in clearly excessive furnishing of controlled substances in violation of Health and Safety Code section 11153 and not for a valid medical purpose, as set forth above in paragraphs 27-29.

SECOND CAUSE FOR DISCIPLINE

(Failure to Exercise Due Caution)

31. Respondents are each and severally subject to discipline under Code sections 4113(c), 4301, subsections (j) and (o), and 4306.5, and under California Code of Regulations, title 16, section 1707.3, in that Respondents committed unprofessional conduct by failure to appropriately exercise the education training and experience of a pharmacist, and failure to exercise or implement professional judgment, and failure to consult appropriate records, in the furnishing of controlled substances, as set forth above in paragraphs 27-29.

THIRD CAUSE FOR DISCIPLINE

(Incomplete Inventory and/or Records of Acquisition and/or Disposition)

32. Respondents are each and severally subject to discipline under Code sections 4113(c), 4301, subsections (j) and (o), and, by reference to section(s) 4081, 4105 and/or 4332 of the Code, and/or California Code of Regulations, title 16, section 1718, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 27-29, Respondents failed to maintain an accurate, complete, and readily retrievable inventory and/or records of acquisition and disposition of all dangerous drugs in the pharmacy inventory.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

33. Respondents are each and severally subject to discipline under section 4301 of the

Code in that Respondents, as described in paragraphs 27-29 above, engaged in unprofessional conduct.

OTHER MATTERS

- 34. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50159, issued to Getwell Pharmacy & Medical Supply Corp., Michael Chikaodinak Acholonu, President, Owner, Pharmacist-in-Charge (Respondent Getwell Pharmacy), then Respondent Getwell Pharmacy 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 50159 is placed on probation or until Pharmacy Permit Number PHY 50159 is reinstated if it is revoked.
- 35. Pursuant to Code section 4307, if discipline is imposed on Respondent Getwell Pharmacy while Michael Chikaodinak Acholonu has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Michael Chikaodinak Acholonu 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 50159 is placed on probation or until Pharmacy Permit Number PHY 50159 is reinstated if it is revoked.
- 36. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 45757, issued to Michael Chikaodinak Acholonu, then Michael Chikaodinak Acholonu shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 45757 is placed on probation or until Pharmacist License Number RPH 45757 is reinstated if it is revoked.

DISCIPLINE CONSIDERATIONS

- 37. To determine the level of discipline, if any, to be imposed on Respondent Acholonu and/or Respondent Getwell Pharmacy (collectively, Respondents), Complainant further alleges that:
 - 38. On or about January 20, 2011, Citation No. CI 2010 45837, with a fine of

\$329,250.00,² was issued to Respondent Getwell Pharmacy for failure(s) to comply with its obligation(s) with regard to storing, accounting for and dispensing controlled substances. That citation is now final and is incorporated by reference as if fully set forth herein.

- 39. On or about January 20, 2011, Citation No. CI 2010 47073, with a fine of \$329,250.00,³ was issued to Respondent Acholonu for failure(s) to comply with his obligation(s) with regard to storing, accounting for and dispensing controlled substances. That citation is now final and is incorporated by reference as if fully set forth herein.
- 40. On or about December 11, 2012, Citation No. CI 2011 52731, with a fine of \$2,500.00,⁴ was issued to Respondent Getwell Pharmacy for failure(s) to comply with its obligation(s) with regard to storing, accounting for and dispensing controlled substances. That citation is now final and is incorporated by reference as if fully set forth herein.
- 41. On or about December 11, 2012, Citation No. CI 2012 54958, with a fine of \$2,000.00,⁵ was issued to Respondent Acholonu for failure(s) to comply with his obligation(s) with regard to storing, accounting for and dispensing controlled substances. That citation is now final and is incorporated by reference as if fully set forth herein.

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 Original Permit Number RPH 45757, issued to Michael Chikaodinaka Acholonu;
- 2. Revoking or suspending Pharmacy License No. PHY 50159, issued to Getwell Pharmacy & Medical Supply Corp., Michael Chikaodinak Acholonu, President, Owner, Pharmacist-in-Charge;
- 3. Prohibiting Getwell Pharmacy & Medical Supply Corp., Michael Chikaodinak Acholonu, President, Owner, Pharmacist-in-Charge from serving as a manager, administrator,

² The amount was subsequently reduced to \$4,250.00.

³ The amount was subsequently reduced to \$15,750.00. ⁴ The amount was subsequently reduced to \$1,500.00.

The amount was subsequently reduced to \$1,350.00.

The amount was subsequently reduced to \$1,750.00.

owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50159 is placed on probation or until Pharmacy Permit Number PHY 50159 is reinstated if Pharmacy Permit Number PHY 50159 is revoked;

- 4. Prohibiting Michael Chikaodinak Acholonu from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50159 is placed on probation or until Pharmacy Permit Number PHY 50159 is reinstated if Pharmacy Permit Number PHY 50159 is revoked;
- 5. Prohibiting Michael Chikaodinak Acholonu from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 45757 is placed on probation or until Pharmacist License Number RPH 45757 is reinstated if Pharmacist License Number RPH is revoked;
- 6. Ordering Respondents to jointly and severally be responsible 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;
 - 7. Taking such other and further action as deemed necessary and proper.

DATED: 10/18/17

VIRGINIA HEROLD

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California *Complainant*