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9	BEFORE THE	
10	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
11	STATE OF C	CALIFORNIA
12	In the Matter of the Accusation Against:	Case No. 3423
13	UPAS PHARMACY, INC., dba UPAS PHARMACY; BRIAN WILLIAM	ACCUSATION
14	McKILLIP, President, Treasurer / Financial Officer, Pharmacist-in-Charge	
15	3332 Third Avenue San Diego, CA 92103	
16	Pharmacy Permit No. PHY 36112	
17	BRIAN WILLIAM McKILLIP,	
18	3541 Ingraham Street San Diego, CA 92109	
19	Pharmacist License No. RPH 32896	
20	Respondents.	•
21	- Teopondonius	
22	Complainant alleges:	
23	PARTIES	
24	1. Complainant Virginia Herold brings this Accusation solely in her official capacity as	
25	the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.	
26	2. On August 9, 1979, the Board issued Pharmacist License Number RPH 32896 to	
27	Respondent Brian William McKillip. The license was in full force and effect at all times relevant	
28	to the charges brought herein and will expire on October 31, 2010, unless renewed. Effective	

April 28, 2002, the license was revoked, but the revocation was stayed for three years while Respondent McKillip was placed and remained on probation.

3. On January 26, 1990, the Board issued Pharmacy Permit Number PHY 36112 to Respondent Upas Pharmacy, Inc. (Upas), to do business as Upas Pharmacy, with Respondent Brian William McKillip as President, Treasurer / Financial Officer, and Pharmacist-in-Charge. The permit was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2011, unless renewed.

JURISDICTION

- 4. This Accusation is brought before the Board, Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 5. Section 4300, subdivision (a) of the Business and Professions Code (Code) provides, in pertinent part, that every license issued may be suspended or revoked.
- 6. Section 4302 of the Code provides that the board may revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.
- 7. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

STATUTORY PROVISIONS

8. Section 4022 of the Code states:

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

- (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use

or order use of the device.

(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.

9. Section 4059, subsection (a), of the Code states:

A person may not furnish any dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

10. Section 4063 of the Code states:

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

11. 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 . . . pharmacy . . . 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.

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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(b) Incompetence.

- (j) The violation of any of the statutes of this state, or 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.

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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 provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

14. Section 11153 of the Health and Safety (H&S) 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 11158 of the H&S Code states in pertinent part:

- (a) Except as provided in Section 11159 or in subdivision (b) of this section, no controlled substance classified in Schedule II shall be dispensed without a prescription meeting the requirements of this chapter. Except as provided in Section 11159 or when dispensed directly to an ultimate user by a practitioner, other than a pharmacist or pharmacy, no controlled substance classified in Schedule III, IV, or V may be dispensed without a prescription meeting the requirements of this chapter.
- (b) A practitioner specified in Section 11150 may dispense directly to an ultimate user a controlled substance classified in Schedule II in an amount not to exceed a 72-hour supply for the patient in accordance with directions for use given by the dispensing practitioner only where the patient is not expected to require any additional amount of the controlled substance beyond the 72 hours. Practitioners dispensing drugs pursuant to this subdivision shall meet the requirements of subdivision (f) of Section 11164.

16. Section 11159.2 of the H&S Code states in pertinent part:

- (a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:
 - (1) Contain the information specified in subdivision (a) of Section 11164.
- (2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

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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.
- (2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.
- (b)(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.
- (2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.
- (3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.
- (c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
- (d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.
 - (e) This section shall become operative on January 1, 2005.
- 19. Section 11167.5 of the H&S Code states in pertinent part:
- (a) An order for a controlled substance classified in Schedule II for a patient of a licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice may be dispensed upon an oral or electronically transmitted prescription. If the prescription is transmitted orally, the pharmacist shall, prior to filling the prescription, reduce the prescription to writing in

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ink in the handwriting of the pharmacist on a form developed by the pharmacy for this purpose. If the prescription is transmitted electronically, the pharmacist shall, prior to filling the prescription, produce, sign, and date a hard copy prescription. The prescriptions shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, license number, and federal controlled substance registration number of the prescriber. The original shall be properly endorsed by the pharmacist with the pharmacy's state license number, the name and address of the pharmacy, and the signature of the person who received the controlled substances for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice. A licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

REGULATORY PROVISIONS

20. California Code of Regulations, title 16 (Regulations), 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.

COST RECOVERY

21. 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.

DRUG

22. Ontak, generic name Denileukin Diftitox, is an anticancer drug classified as a dangerous drug by Code section 4022.

FACTUAL ALLEGATIONS PERTAINING TO JULY 6, 2007 COMPLAINT

23. On July 6, 2007, the Board received a written complaint from the Department of Healthcare Services (DHS). The DHS alleged Upas was filling prescriptions without a written order, in violation of H&S Code, sections 11153 and 11158, and that the filling of the

prescriptions without a written order did not fall within the exceptions under H&S Code, sections 11159.2 and 11167.5. The Board investigated the written complaint and found as follows.

- 24. The Board's Inspector examined the prescription files of the Schedule II drugs and discovered that Upas was filling faxed and oral prescriptions for Schedule II drugs and the pharmacists at Upas were writing in the exemption under H&S Code, section 11159.2. A pharmacist and pharmacy technician employed by Upas informed the Inspector that the prescriptions were faxed and telephoned into Upas from a cancer center, that Upas filled and delivered the prescriptions to the patients, and later obtained the prescriptions from the cancer center office once weekly. The pharmacist told the Inspector that Respondent McKillip had told him that the Drug Enforcement Administration (DEA) had given him permission to follow this less formal procedure because these were cancer patients, even though the pharmacist had informed Respondent McKillip that this was wrong.
- 25. On June 18, 2008, the Inspector requested and received from DHS a printout of the Medi-Cal billing for the drug, Ontak, for Upas for the period from June 1, 2006, through August 31, 2006. The printout showed that during this period Upas billed and was paid for 84 ml of Ontak, which is 7 boxes, each containing 6 vials x 2ml Ontak 150.
- 26. On June 20, 2008, the Inspector received a written statement he had requested from Respondent McKillip regarding an audit and unauthorized prescriptions for patients of a Dr. S. In it, McKillip stated he was told by a physician that the H&S Code section 11159.2 exemption could be used for terminally ill patients, but during the audit realized that three to four patients did not meet the requirements of this provision. McKillip stated Upas was now picking up the prescriptions daily, and that he did not fully comprehend the law regarding section 11159.2.
- 27. On June 15, 2008, the Inspector received the patient profiles produced by Upas showing that patient Myrtle G. had received 12ml (or 1 box of 6 x 2ml) of Ontak on 8/8/06, 8/3/06, 8/1/06, 7/11/06 7/31/06, 7/10/06 and 7/6/06, which were billed to Medi-Cal, and 6 ml on 6/29/06 and 6/26/06, which were billed to CMS (County Medical Services) for a total of 8 vials. The Inspector also received a copy of DHS' July 31, 2007 letter to Upas, which showed Medi-Cal was billed for 7 boxes of Ontak; and three invoices from Cardinal Health to Upas for Ontak

purchases. However, comparison of the invoices to the Medi-Cal billing and to Myrtle G.'s patient profile revealed that Upas was shorted and overbilled for 2 boxes of Ontak, in violation of the record and inventory requirements of Code section 4081 and Regulations, section 1718.

- 28. On July 3, 2008, the Inspector entered the prescriptions for Schedule II drugs obtained from Upas into a spread sheet. Analysis of that data shows that out of 194 prescriptions:
 - a. 62 schedule II controlled substances prescriptions were faxed to Upas and dispensed in violation of H&S Code, section 11167.5, subdivision (a), 47 of which were processed by RPH McKillip, 4 by RPH Perry, and 11 by RPH Frank;
 - b. Upas dispensed 117 schedule II controlled substance prescriptions by adding the wording "11159.2 exemption," in violation of H&S Code, section 11159.2 subdivision (a)(2), 66 of which were processed by RPH McKillip, 24 by RPH Perry, and 27 by RPH Frank; and
 - c. Upas dispensed 128 oral prescriptions of Schedule II drugs, of which 74 were processed by RPH McKillip, 32 by RPH Perry, and 21 by RPH Frank.
- 29. On July 29, 2008, the Inspector sent a Written Notice of violations charged to Respondents Upas and McKillip. On August 20, 2008, McKillip's counsel faxed a reply to the Written Notice to the Inspector, which the Board received on August 22, 2008. Though the reply was a statement signed by McKillip under penalty of perjury, it was substantively only a repeat of his June 20, 2008 statement, described in paragraph 26, above.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Furnishing Without A Prescription)

30. Respondents Upas Pharmacy and McKillip are subject to disciplinary action under section 4301, subdivisions (j) and (o) of the Code for violation of the Pharmacy Act and laws regulating drugs in that they furnished prescription medications without prescriptions therefor, or without proper exemptions from the prescription requirement, in violation of Code section 4059, and H&S Code section 11167.5, subdivision (a), and as detailed in paragraphs 23-29, above.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Incompetence)

32. Respondent McKillip's pharmacist license is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (b) for incompetence, because in managing the operations of Upas, and in filling prescriptions, he demonstrated that he lacked the

requisite knowledge, ability, or skill of a competent PIC to practice pharmacy within the standard of care governing pharmacists, as detailed in paragraphs 23-29, above.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Dangerous Drugs Acquisition Records and Current Inventory)

33. Respondents Upas and McKillip are subject to disciplinary action under section 4301, subdivision (o) of the Code for violation of the Pharmacy Act and Regulations, in that they failed to maintain purchase records for two vials of Ontak, 150 mcg, resulting in an inaccurate inventory in violation of Regulations, section 1718, and Code section 4081, subdivision (a), as detailed in paragraphs 23-29, above.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Produce or Provide Pharmacy Records)

34. Respondents Upas and McKillip are subject to disciplinary action under section 4301, subdivision (o) of the Code for violation of the Pharmacy Act in that they failed, neglected, or refused to provide invoices to the Pharmacy Inspector for two vials of Ontak 150mcg, in violation of Code, sections 4081, subdivision (a), and 4332, as detailed in paragraphs 23-29, above.

FACTUAL ALLEGATIONS PERTAINING TO DECEMBER 12, 2007 COMPLAINT

- 35. On December 12, 2007, the Board received an on-line complaint from the office of Dr. S., a physician with offices located up the street from Respondent Upas. Dr. S. alleged that Respondents Upas and McKillip were filling prescriptions without authorization from his office. Dr. S.'s office staff stated some of their patients receiving prescriptions without authorization were Joanne C., Cheryl T., Jennifer A., and Carl H.
- 36. During his May 30, 2008, visit to Upas, the Inspector completed an Inspection Report and asked to see the Doctor's Utilization Report (DUR) for Dr. S. for all patients for the last two years, and patient profiles for Joanne C., Cheryl T., Jennifer A., Carl H., Ronald F., Theresa H., and Marizel P., including prescription numbers, dates, drugs, third party insurance, and patient addresses information.
- 37. On June 15, 2008, the Inspector received the patient profiles for Ronald F., Marizel P., Theresa H., Carl H., Joanne C., Jennifer A., and Cheryl T.; and the DUR for Dr. S. On June

18, 2008, the Inspector sent a letter to Dr. S. with the patient profiles of Carl H., Joanne C., Cheryl T., and Jennifer A., asking him to determine if the prescription refills allegedly authorized by him were in fact authorized by him. On July 17, 2008, the Inspector received Dr. S.'s reply, which included the patient profiles for Carl H. Jennifer A., Cheryl T., and Joanne C. The Inspector's review of these documents showed that:

- a. Upas filled seven unauthorized prescriptions for Carl H.;
- b. Upas filled seven unauthorized prescriptions for Jennifer A.;
- c. Upas filled eleven unauthorized prescriptions for Cheryl T.; and
- d. Upas filled two unauthorized prescriptions for Joanne C.
- 38. On July 29, 2008, the Inspector sent a Written Notice of violations charged to Respondents Upas and McKillip. On August 20, 2008, McKillip's counsel faxed a reply to the Written Notice to the Inspector, which the Board received on August 22, 2008. Though the reply was a statement signed by McKillip under penalty of perjury, it was substantively only a repeat of his June 20, 2008 statement, described in paragraph 26, above.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Violating Pharmacy Laws)

39. Respondents Upas Pharmacy and McKillip are subject to disciplinary action under section 4301, subdivision (o) of the Code for violation of the Pharmacy Act, in that they furnished prescription medications without prescriptions therefor, in violation of Code section 4059, subdivision (a), as detailed in paragraphs 35—38, above.

SIXTH CAUSE FOR DISCIPLINE

(Filing of Non-Compliant Schedule II Prescriptions)

40. Respondents Upas and McKillip are subject to disciplinary action under section 4301, subdivisions (j) and (o) of the Code for violation of the Pharmacy Act and laws regulating drugs in that they filled 25 prescriptions for controlled substances and dangerous drugs without the authorization of the prescriber, in violation of Code section 4063, and H&S Code, sections 11158 and 11167.5, subdivision (a), as detailed in paragraphs 35—38, above.

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DISCIPLINARY CONSIDERATIONS

To determine the degree of discipline, if any, to be imposed on Respondents, 41. Complainant alleges that on April 28, 2002, in a prior proceeding on Accusation Case No. 2396, Respondents Upas and McKillip admitted the truth of the allegations pled against them in Accusation Case No. 2396, and agreed that their Pharmacy Permit and Pharmacist License were subject to discipline and to be bound by the Board's revoking Respondents' permit and pharmacy license, stayed for three years; suspending Respondent McKillip's license for 120 days; ordering Respondents to pay the Board \$4,152 as costs; and additional terms of probation as set forth in the Disciplinary Order of that date, a true and correct copy of which is attached as Exhibit A.

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:

- Revoking or suspending Pharmacy Permit Number PRY 32896 issued to Upas 1. Pharmacy, Inc., dba Upas Pharmacy, Brian William McKillip, President, Treasurer / Financial Officer, Pharmacist-in-Charge;
- Revoking or suspending Pharmacist License Number RPH 36112, issued to Brian W. 2. McKillip, RPH;
- Ordering Brian W. McKillip, RPH and/or Upas Pharmacy, Inc., dba Upas Pharmacy, Brian William McKillip, President, Treasurer / Financial Officer, Pharmacist-in-Charge 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:
 - Taking such other and further action as deemed necessary and proper.

DATED: 6/9/10

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant