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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. 3480

12 **SOUTHWOOD PHARMACEUTICAL**
13 **60 Empire Drive**
Lake Forest, CA 92630
14 **Wholesale Permit No. WLS 4078**

A C C U S A T I O N

15 **JOHN SEMPRES**
16 **60 Empire Drive**
Lake Forest, CA 92630
17 **Pharmacist License No. RPH 25420**

18 **MEDIPHARM RX INC.**
19 **4607 N. Clark Avenue**
Tampa, FL 33614
20 **Non-Resident Pharmacy License No.**
NRP 670

21 **UNITED PRESCRIPTION SERVICES**
22 **2304 East Fletcher Avenue**
Tampa, FL 33612
23 **Non-Resident Pharmacy License No.**
NRP 466

24 **MEDCENTER INC.**
25 **6935 S. Carter Road, Suite 6 and 7**
Lakeland, FL 33813
26 **Non-Resident Pharmacy License No.**
NRP 752

27 Respondents.
28

1 Complainant alleges:

2 **PARTIES**

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

5 2. On or about March 25, 2002, the Board of Pharmacy issued Original Wholesale
6 Permit Number WLS 4078 to Southwood Pharmaceutical, Inc. (Respondent Southwood). The
7 Original Wholesale Permit was in full force and effect at all times relevant to the charges brought
8 herein and will expire on March 1, 2011, unless renewed.

9 3. On or about March 7, 1968, the Board of Pharmacy issued Pharmacist License
10 Number RPH 25420 to John Sempre (Respondent Sempre). The Pharmacist License was in full
11 force and effect at all times relevant to the charges brought herein and will expire on January 31,
12 2011, unless renewed.

13 4. On or about January 5, 2006, the Board of Pharmacy issued Non-Resident Pharmacy
14 License Number 670 to Medipharm Rx Inc. (Respondent Medipharm). The Non-Resident
15 Pharmacy License expired on January 1, 2007, and has not been renewed.

16 5. On or about May 3, 2002, the Board of Pharmacy issued Non-Resident Pharmacy
17 Number 466 to United Prescription Services (Respondent UPS). The Non-Resident Pharmacy
18 License expired on May 1, 2005, and has not been renewed.

19 6. On or about October 3, 2006, the Board of Pharmacy issued Non-Resident Pharmacy
20 Number 752 to Medcenter Inc. (Respondent Medcenter). The Non-Resident Pharmacy License
21 expired on October 1, 2007, and has not been renewed.

22 **JURISDICTION**

23 7. This Accusation is brought before the Board of Pharmacy (Board), Department of
24 Consumer Affairs, under the authority of the following laws. All section references are to the
25 Business and Professions Code unless otherwise indicated.

26 8. Section 4300 of the Code provides that every license issued by the Board may be
27 suspended or revoked.
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1 9. Section 4402(e) of the Code provides, in pertinent part, that any license, other than a
2 pharmacist license, issued by the board may be canceled by the board if the license is not renewed
3 within 60 days after its expiration. Any license canceled under this subdivision may not be
4 reissued. Instead, a new application will be required.

5 10. Section 118, subdivision (b), of the Code provides that the suspension, expiration,
6 surrender or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a
7 disciplinary action during the period within which the license may be renewed, restored, reissued
8 or reinstated.

9 **STATUTORY PROVISIONS**

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

11 The board shall take action against any holder of a license who is guilty of unprofessional
12 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

13 Unprofessional conduct shall include, but is not limited to, any of the following:

14

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

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

22 12. Section 4022 of the Code states

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

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

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

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

6 13. Section 4022.5 of the Code states, in pertinent part:

7 (a) "Designated representative" means an individual to whom a license has been granted
8 pursuant to section 4053. A pharmacist fulfilling the duties of section 4053 shall not be required
9 to obtain a license as a designated representative.

10 (b) "Designated representative-in-charge" means a designated representative or a
11 pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the
12 board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-
13 animal drug retailer's compliance with all state and federal laws and regulations pertaining to
14 practice in the applicable license category.

15 REGULATORY PROVISIONS

16 14. California Code of Regulations, Title 16, section 1708.2 states that any permit holder
17 shall contact the board prior to transferring or selling any dangerous drugs, devices or
18 hypodermics inventory as a result of termination of business or bankruptcy proceedings and shall
19 follow official instructions given by the board applicable to the transaction.

20 15. United States Code, Title 21, section 823(d) states, in pertinent part, that the Attorney
21 General shall register an applicant to manufacture controlled substances in schedule III, IV, or V,
22 unless he determines that the issuance of such registration is inconsistent with the public interest.
23 In determining the public interest, the following factors shall be considered:

24 (1) maintenance of effective controls against diversion of particular controlled substances
25 and any controlled substance in schedule III, IV, or V compounded therefrom into other than
26 legitimate medical, scientific, or industrial channels;

27 (2) compliance with applicable State and local law;

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1 (3) promotion of technical advances in the art of manufacturing these substances and the
2 development of new substances;

3 (4) prior conviction record of applicant under Federal or State laws relating to the
4 manufacture, distribution, or dispensing of such substances;

5 (5) past experience in the manufacture, distribution, and dispensing of controlled
6 substances, and the existence in the establishment of effective controls against diversion; and

7 (6) such other factors as may be relevant to and consistent with the public health and
8 safety.

9 16. United States Code, Title 21, section 824(a) (4) states, in pertinent part, that a
10 registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled
11 substance or a list I chemical may be suspended or revoked by the Attorney General upon a
12 finding that the registrant has committed such acts as would render his registration under section
13 823 of this title inconsistent with the public interest as determined under such section.

14 COST RECOVERY

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

19 DRUGS

20 18. **Phentermine** (brand name **Fastin**) is a Schedule IV controlled substance as
21 designated by Health and Safety Code section 11057(f)(4) and a dangerous drug as designated by
22 Business and Professions Code section 4022. It is a stimulant drug indicated for weight loss.

23 19. **Alprazolam** (brand name **Xanax**) is a Schedule IV controlled substance as
24 designated by Health and Safety Code section 11057(d) (1) and a dangerous drug as designated
25 by Business and Professions Code section 4022. It is a depressant drug indicated for anxiety.

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1 20. **Hydrocodone with acetaminophen** (brand name **Vicodin**) is a Schedule III
2 controlled substance as designated by Health and Safety Code section 11056(e) (4) and a
3 dangerous drug as designated by Business and Professions Code section 4022. It is a narcotic
4 indicated for moderate pain.¹

5 **FACTS**

6 21. On March 25, 2002, the Board issued a drug wholesale permit, WLS 4078, to
7 Respondent Southwood. Respondent Sempre was the owner and designated representative in
8 charge at Southwood. The Drug Enforcement Administration (DEA) also issued Respondent
9 Southwood a DEA Certificate of Registration to purchase and sell controlled substances as a
10 repackager, RS0204898.

11 22. Respondent Southwood had a repackaging license with the Food and Drug
12 Administration (FDA), license no. 2027647, and with the Department of Health Care Service,
13 State Food and Drug Branch, license no. 42125. Respondent Southwood repackaged oral dose
14 generic drugs into common prescription quantities. Respondent Southwood's customers included
15 physicians who specialized in treating work-related injuries, pain management, urgent care
16 facilities, specialty clinics and retail pharmacies.

17 23. In or around July 2006, the DEA began conducting an investigation into Respondent
18 Southwood when the DEA received information that Respondent Southwood's sales of
19 hydrocodone products increased from 7,000 dosage units per month to 3,700,000 dosage units per
20 month.

21 24. In or around July 2006, M.M., Chief of the Office of Diversion Control's E-
22 Commerce Section from the DEA, conducted a conference call with Robert Goodrich, the
23 Director of Operations and Regulatory Affairs and Grace Gonzalez, Operations Manager of
24 Respondent Southwood.

25 _____
26 ¹ By itself, hydrocodone is a Schedule II controlled substance. Respondent did not,
27 however, distribute Schedule II hydrocodone. Throughout this Accusation, the term hydrocodone
28 refers to those Schedule III controlled substances which contain hydrocodone, pursuant to Health
and Safety Code section 11056, and a dangerous drug as designated by Business and Professions
Code section 4022.

1 25. M.M. discussed the requirement under Federal Law that in order for a prescription to
2 be valid, it must be issued in the usual course of medical practice, and that an internet
3 questionnaire alone is not sufficient to legally prescribe controlled substances.

4 26. Respondent Southwood was advised that factors necessary to establish a bona fide
5 doctor-patient relationship included that the patient have a medical complaint; a history be taken
6 of the patient; a physical examination be conducted; and that there be a nexus between the
7 complaint, the history, the examination, and the drug being prescribed.

8 27. Mr. Goodrich was also informed that a pattern of drugs being distributed to
9 pharmacies which were diverted controlled substances demonstrated a lack of effective controls
10 against diversion by the distributor.

11 28. Mr. Goodrich was also advised that any distributor selling controlled substances that
12 are being dispensed outside of the course of professional practice must stop the distribution
13 immediately, and that Respondent Southwood had an obligation to ensure the products distributed
14 were used for legitimate medical purposes.

15 29. After the conference with the DEA, Respondent Southwood continued to distribute
16 large quantities of hydrocodone to numerous internet pharmacies.

17 30. On or about December 6, 2006, R.P., Acting Special Agent in Charge of the DEA,
18 Los Angeles Field Division, announced the immediate suspension of Respondent Southwood's
19 DEA Certificate of Registration. Respondent Southwood had been the subject of a DEA
20 investigation alleging that Respondent Southwood sold large quantities of controlled substances
21 to internet pharmacies.

22 31. For the purpose of the DEA's investigation, the term "internet pharmacy" was
23 referred to as a pharmacy that filled a prescription issued by physician without the physician
24 having entered into a legitimate doctor-patient relationship under existing professional standards.²

25 ² Typically, a person seeking controlled substances goes to an internet site, fills out a
26 questionnaire which requests basic medical, payment and shipping information, and a specific
27 drug. Some websites may require the patient submit a medical record, which is easily falsified.
28 The customer's information is forwarded to a physician either contracted or employed by the
website, who reviews the information and issues a prescription, either with or without the benefit
of a perfunctory telephone consultation, but always without having conducted a face-to-face

(continued...)

1 32. On or about December 29, 2006, the Board received information from the DEA
2 notifying the Board that Respondent Southwood's license with the DEA was suspended on the
3 basis of diversion of controlled substances. Respondent Southwood was the subject of a DEA
4 investigation alleging that the company sold large quantities of controlled substances to internet
5 pharmacies.

6 33. On or about June 22, 2007, Administrative Law Judge (ALJ) Michele Leonhart
7 ordered the DEA Certificate of Registration, RS0204898, issued to Respondent Southwood, be
8 revoked and the pending application of Respondent Southwood for renewal of its registration be
9 denied. ALJ Leonhart concluded that Respondent Southwood's continued registration constituted
10 an imminent danger to public health and safety. The order was effective immediately.

11 34. The DEA website www.deadiversion.usdoj.gov posted on the Federal Register
12 Notices, dated July 3, 2007, Volume 72, Number 127, Docket No. 07-7, titled: "Southwood
13 Pharmaceuticals, Inc., Revocation of Registration." The docket stated the following:

14 a. On November 30, 2006, the Deputy Administration of the DEA issued an Order to
15 Show Cause and Immediate Suspension of Registration to Southwood. The Order immediately
16 suspended Southwood's DEA Certificate of Registration, RS0204898, based on preliminary
17 findings that continued registration constituted an imminent danger to the health and safety of the
18 public due to the substantial likelihood that Southwood would continue to supply pharmacies that
19 diverted large quantities of controlled substances;

20 b. The Show Cause Order alleged that between November 2005 and August 2006,
21 Southwood sales to pharmacies for hydrocodone products increased from approximately 7,000
22 dosage units per month to approximately 3,000,000 dosage units per month and the increase was
23 directly attributable to supplying controlled substances to pharmacies that Southwood should
24 have known were engaged in the widespread diversion of controlled substances. The Show

25
26 review of the person's medical history and a physical exam. The prescription is then either
27 forwarded to the pharmacy or downloaded electronically by the pharmacy; the pharmacy then
28 fills the prescription and ships it to the customer.

1 Cause Order alleged several customers were distributing large amounts of hydrocodone-based
2 orders placed by customers using various websites.

3 c. The Show Cause Order specifically alleged that from December 12, 2005 to
4 August 31, 2006, Southwood distributed approximately 8,671,000 dosage units of hydrocodone
5 products to Medipharm-Rx, Inc., and did so under circumstances that clearly indicated that
6 Medipharm, whose owner also owned an internet website, engaged in the diversion of controlled
7 substances. Medipharm was soliciting orders for controlled substances, used practitioners who
8 issued prescriptions outside of their usual professional practice, and Medipharm's orders were of
9 an unusual size and frequency, deviating from the normal pattern. In addition to Medipharm,
10 Southwood also sold drugs to fourteen pharmacies with similar suspicious circumstances. The
11 Show Cause Order alleged that Southwood had repeatedly supplied excessive quantities of
12 hydrocodone to pharmacies it knew or should have known were diverting hydrocodone.

13 d. The next Show Cause Order alleged that on July 17, 2006, the Office of Diversion
14 Commerce Section held a conference call with Southwood representatives to discuss the
15 distribution of controlled substances to internet pharmacies. During the call, DEA officials
16 allegedly presented Southwood with information on the characteristics of internet pharmacies and
17 the nature of their illegal activities. In August 2006, Southwood proceeded to distribute large
18 quantities of hydrocodone to five different internet pharmacies and allegedly failed to maintain
19 effective control against diversion, and Southwood's continued registration would be inconsistent
20 with the public interest.

21 e. From February 5 through February 8, 2007, a hearing was conducted in Arlington,
22 VA., by ALJ Gail Randall. On March 30, 2007, the ALJ issued her recommended decision,
23 concluding that the DEA had proved that Southwood's continued registration to handle
24 hydrocodone would be against the public interest. The ALJ concluded that Southwood had kept
25 an open dialogue with the DEA and had attempted to come into compliance with the DEA's
26 regulations and revocation of Southwood's DEA registration was too severe a remedy. The ALJ
27 noted that Southwood had hired an experienced officer who would be making the final decisions
28 concerning compliance measures, providing an increased level of protection of the public interest.

1 Therefore, the ALJ recommended that Southwood's authority to handle hydrocodone products be
2 revoked while allowing Southwood to retain its authority to handle other controlled substances.
3 The ALJ recommended the DEA monitor Southwood to ensure it complied with both the
4 proposed restrictions and Southwood's decision to cease distributing to Florida-based internet
5 pharmacies.

6 f. Thereafter, the U.S. Government filed exceptions, stating that Southwood also
7 distributed excessive quantities of other controlled substances including phentermine and
8 alprazolam. The Government further argued that under the day-to-day leadership of Southwood's
9 new Chief Operating Officer (COO), Southwood continued to constructively distribute controlled
10 substances to its physician clients after its registration was suspended, refuting the ALJ's
11 hypothesis that the COO would effectively manage Southwood's compliance program.

12 g. On May 8, 2007, the ALJ forwarded the record to Michele Leonhart, Deputy
13 Administrator, who adopted the ALJ's findings, but concluded that the ALJ's proposed remedy
14 was insufficient to protect the public interest, and that Respondent's sales of extraordinary
15 quantities of controlled substances to entities which it had reason to know were diverting drugs
16 caused extraordinary harm to public health and safety. Therefore, Southwood's registration was
17 revoked and its pending renewal application was denied.

18 35. The DEA's findings that lead to the revocation of Southwood's DEA registration,
19 listed in Docket No. 07-7, also included the following:

20 a. From August 2005, the DEA reviewed the ARCOS (Automation of Reports and
21 Consolidated Orders System) reports submitted by Southwood. Southwood had sold 3,949,454
22 dosage units of hydrocodone products, of which, 3,882,507 dosage units (98%) were sold to
23 practitioner customers and 29,940 dosage units (0.75%) to pharmacy customers, for an average of
24 7,485 dosage units per month.

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1 b. On December 7, 2005, Southwood entered a new line of business- supplying
2 internet pharmacies- by selling hydrocodone to Medipharm-Rx., Inc., a Florida-based internet
3 pharmacy (Respondent Medipharm). Over the ensuing months, Southwood acquired numerous
4 additional internet pharmacy customers to whom it repeatedly sold large quantities of
5 hydrocodone.

6 c. On December 7, 2005, Southwood began supplying Medipharm-Rx Inc. and other
7 internet pharmacies with hydrocodone products. From December 2005 through October 2006,
8 Southwood supplied Medipharm with 11,130,700 dosage units of hydrocodone products, an
9 average of 1,011,882 dosage units of hydrocodone products per month, constituting 99% of drug
10 sales to Medipharm.

11 d. The Florida Board of Pharmacy, website www.doh.state.fl.us, revealed that
12 Medipharm-Rx had two licenses (PH21003 and PH21000) at the same address that both listed
13 "closed" as the license activity status. The California State Board of Pharmacy, website
14 www.pharmacy.ca.gov, listed Medipharm-Rx, Inc., license no. NRP670, as expired on January 1,
15 2007. Medipharm failed to renew their non-resident pharmacy license, had a "delinquent" status,
16 and failed to submit a discontinuance of business with the Board of Pharmacy.

17 e. On December 19, 2005, Southwood began supplying Accumed Rx., Inc., another
18 internet Florida-based pharmacy customer. From December 2005 to November 2006, Southwood
19 sold 5,884,212 dosage units of hydrocodone products to Accumed, constituting 99% of drug sales
20 to Accumed.

21 f. The Florida Board of Pharmacy revealed that Accumed-Rx had one license
22 (PH21402) listed "closed" as the license activity status. The California State Board of Pharmacy
23 showed no listing for Accumed-Rx.

24 g. On December 21, 2005, Southwood started supplying Avee Pharmacy, another
25 internet pharmacy. From December 2005 through November 2006, Southwood supplied Avee
26 with 6,795,110 dosage units of hydrocodone products plus 238,140 dosage units during the first
27 five days of December 2006. From December 2005 to June 2006, controlled substances
28 constituted 100% of sales to Avee. On or about November 17, 2006, Southwood notified Avee

1 by letter effective December 15, 2006, Southwood would not supply Avee (whose registration
2 had been continued on a day-to-day basis past its expiration date and not renewed) unless it
3 obtained a renewal of its registration. Between November 17, 2006 to December 15, 2006,
4 Southwood supplied Avee approximately 6,795,110 dosage units of hydrocodone products.

5 h. The Florida Board of Pharmacy revealed that Avee Pharmacy had two licenses
6 (PH19760 and PH21935) both listed "closed" as the license activity status. The California State
7 Board of Pharmacy listed Avee Pharmacy as a non-resident pharmacy, license no. NRP657, as
8 "cancelled."

9 i. On January 4, 2006, Southwood began supplying United Prescription Services,
10 Inc., (Respondent UPS), another internet pharmacy. From February 2006 to November 2006,
11 Southwood sold 929,880 dosage units to UPS, a monthly average of 92,988 dosage units. On
12 November 17, 2006, Southwood notified UPS that it would stop supplying UPS if UPS did not
13 obtain a renewal of its registration. From November 21, 2006 through December 5, 2006,
14 Southwood sold 158,280 dosage units of hydrocodone to UPS.

15 j. The Florida Board of Pharmacy revealed that UPS had two licenses (PH17181 and
16 PH24549) - the first, listed as "closed" as the license activity status, and the second as
17 "null/void." The California State Board of Pharmacy listed UPS as a non-resident pharmacy,
18 license no. NRP466, as "delinquent." UPS' license was issued May 3, 2002 and expired on May
19 1, 2005. UPS failed to renew their non-resident pharmacy license, had a "delinquent" status, and
20 failed to submit a discontinuance of business with the Board of Pharmacy.

21 k. On January 25, 2006, Southwood began servicing Bi-Wise Drugs, Inc. (Bi-Wise),
22 another internet pharmacy customer. From January 25, 2006 through October 2006, Southwood
23 sold 1,171,500 dosage units to Bi-Wise, a monthly average of 117,150 dosage units.

24 l. Bi-Wise had three licenses with the Florida Board of Pharmacy (PH21960,
25 PH18991, and PH22277), all listed as "closed." Bi-Wise was also doing business as Bi-Wise
26 Pharmacy and Compounding. Bi-Wise was not listed as a non-resident pharmacy with the
27 California State Board of Pharmacy.

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1 m. On February 16, 2006, Southwood began servicing Vin-Kash, dba Medicom Rx
2 (Medicom), another internet pharmacy customer. From February 2006 through November 2006,
3 Medicom purchased 1,902,810 dosage units of hydrocodone from Southwood, a monthly average
4 of 190,281 dosage units.

5 n. The Florida Board of Pharmacy listed Medicom's license (PH21018) as
6 "delinquent." Medicom was not licensed in California as a non-resident pharmacy.

7 o. On February 20, 2006, Southwood began servicing Discount Mail Meds
8 (Discount), another internet pharmacy customer. From February 2006 through November 2006,
9 Discount purchased 3,303,240 dosage units of hydrocodone products from Southwood, a monthly
10 average of 330,324 dosage units. Discount was not listed on the Florida Board of Pharmacy
11 website as a pharmacy licensed in Florida; nor was it listed on the California State Board of
12 Pharmacy website as either a pharmacy or a non-resident pharmacy licensed in California.

13 p. On February 22, 2006, Southwood began servicing Universal Rx (Universal).
14 From February 2006 to November 2006, Universal purchased 3,086,790 dosage units of
15 hydrocodone products from Southwood, a monthly average of 308,679 dosage units. On
16 November 17, 2006, Southwood notified Universal that effective December 15, 2006, it would
17 stop supplying the pharmacy unless it obtained a renewal of its registration. On November 30,
18 2006, Southwood stopped shipping to Universal.

19 q. The Florida Board of Pharmacy website listed Universal (license no. PH19719) as
20 "delinquent." Universal was not listed on the California State Board of Pharmacy website as a
21 pharmacy or a non-resident pharmacy licensed in California.

22 r. On March 3, 2006, Southwood began doing business with Medcenter, Inc.
23 (Respondent Medcenter), an entity owned by the same person as Medipharma. From March 2006
24 through October 2006, Medcenter purchased 2,664,500 dosage units of hydrocodone products
25 from Southwood, a monthly average of 333,062 dosage units. In November 2006, when
26 Medcenter's DEA registration was suspended, Southwood sold Medcenter 313,680 dosage units
27 of hydrocodone products during the first two weeks of November.

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1 s. The Florida Board of Pharmacy website listed Medcenter (license no. PH21072) as
2 "delinquent." The California State Board of Pharmacy listed Medcenter Pharmacy as a non-
3 resident pharmacy, license no. NRP752, as "delinquent." Medcenter's license was issued
4 October 3, 2006 and expired on October 1, 2007. Medcenter failed to renew their non-resident
5 pharmacy license, had a "delinquent" status, and failed to submit a discontinuance of business
6 with the Board of Pharmacy.

7 t. On March 9, 2006, Southwood began doing business with CRJ Pharmacy, Inc.
8 (CRJ). From March 2006 to October 2006, Southwood sold CRJ 638,420 dosage units of
9 hydrocodone products, a monthly average of 79,803 dosage units.

10 u. The Florida Board of Pharmacy website listed CRJ (license no. PH21511) as
11 "closed." CRJ was not licensed in California as a non-resident pharmacy.

12 v. In May 2006, Southwood began doing business with Akshar Chemists, dba
13 Medicine Shoppe. From May 2006 to November 2006, Southwood sold Medicine Shoppe
14 513,555 dosage units of hydrocodone products, a monthly average of 73,365 units.

15 w. The Florida Board of Pharmacy website listed Medicine Shoppe (license no.
16 PH18507) as "closed." Medicine Shoppe was not licensed in California as a non-resident
17 pharmacy.

18 x. In May 2006, Southwood began doing business with Grand Pharmacy (Grand).
19 From May 2006 to November 2006, Southwood sold Grand 1,008,720 dosage units of
20 hydrocodone products, a monthly average of 144,102 units.

21 y. The Florida Board of Pharmacy website listed Grand (license no. PHY21636) as
22 "closed." Grand was not licensed in California as a non-resident pharmacy.

23 z. In July 2006, Southwood began doing business with Q-R-G, Inc., dba Duane's
24 Discount Group (Duane's). From July to November 2006. From July 2006 to November 2006,
25 Southwood sold Duane's 959,040 dosage units of hydrocodone products, a monthly average of
26 191,808 units.

27 aa. The Florida Board of Pharmacy website listed Duane's (license no. PH21512) as
28 "closed." Duane's was not licensed in California as a non-resident pharmacy.

1 36. Docket No. 07-7 listed the following due diligence efforts of Southwood:

2 a. Southwood's due diligence in approving a new customer was limited to verifying
3 that the customer had a state license and a DEA registration. Based solely on its verification of
4 the customer's DEA registration and state license, Southwood would commence shipping large
5 quantities of controlled substances to various internet pharmacies.

6 37. On or about September 6, 2007, an inspector for the California State Board of
7 Pharmacy went to Southwood to conduct an inspection and investigation. Respondent Sempre
8 was present during this investigation. At the end of the inspection, a copy of the inspection report
9 was signed by Respondent Sempre. Two corrections were ordered to revise policy and
10 procedures for Southwood's standard operations procedure: documentation of how long records
11 of acquisition and disposition were retained; and revision of standard operations procedure for
12 theft and loss to include contacting the Board within 30 days.

13 38. On or about January 6, 2009, Southwood's application for a new DEA registration
14 number was approved, and on January 7, 2009, DEA registration number RS0377691 was issued
15 with restrictions. (Southwood's original registration number DEA RS0204898 remained
16 revoked). Southwood's new DEA registration number authorized Southwood to sell Schedule III,
17 IV and V controlled substances to hospitals, clinics, and physicians dispensing from their offices.
18 Southwood was not given authorization to sell to pharmacies.

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1 **FIRST CAUSE FOR DISCIPLINE**

2 **(Unprofessional Conduct-Violation of California and United States Code)**

3 39. Respondent Southwood is subject to disciplinary action for unprofessional conduct
4 under section 4301, subdivisions (j) and (o) of the Code, in conjunction with Title 21 U.S.C.
5 section 823(d) and 824(a)(4), for violation of the Pharmacy Act and laws regulating controlled
6 substances in that between November 2005 to December 2006, Respondent Southwood sold large
7 quantities of controlled substances to several pharmacies dispensing internet prescriptions for
8 hydrocodone products, a Schedule III controlled substance, and other controlled substances, and
9 continued to sell to these internet pharmacies after Respondent Southwood was educated on the
10 requirements for a valid prescription by the DEA, demonstrating a lack of effective control
11 against diversion. On or about June 22, 2007, Respondent Southwood's DEA controlled
12 substance registration (RS0204898) was revoked and Respondent Southwood's pending
13 application for renewal was denied after conclusion that Southwood's continued registration
14 constituted an imminent danger to public health and safety in violation of pharmacy law and as
15 detailed in paragraphs 21-38, above.

16 **SECOND CAUSE FOR DISCIPLINE**

17 **(Unprofessional Conduct-Violation of California and United States Code)**

18 40. Respondent Sempre is subject to disciplinary action for unprofessional conduct under
19 section 4301(j) and (o), and 4022.5 of the Code, in conjunction with Title 21 U.S.C. section
20 823(d) and 824(a)(4), for violation of the Pharmacy Act and laws regulating controlled substances
21 in that between November 2005 to December 2006, Respondent Southwood sold large quantities
22 of controlled substances to several pharmacies dispensing internet prescriptions for hydrocodone
23 products, a Schedule III controlled substance, and other controlled substances, and continued to
24 sell to these internet pharmacies after Respondent Southwood was educated on the requirements
25 for a valid prescription by the DEA, demonstrating a lack of effective control against diversion.
26 On or about June 22, 2007, Respondent Southwood's DEA controlled substance registration
27 (RS0204898) was revoked and Respondent Southwood's pending application for renewal was
28 denied after conclusion that Southwood's continued registration constituted an imminent danger

1 to public health and safety in violation of pharmacy law and as detailed in paragraphs 21-38,
2 above.

3 **THIRD CAUSE FOR DISCIPLINE**

4 **(Unprofessional Conduct)**

5 41. Respondents Southwood and Sempre are subject to disciplinary action for
6 unprofessional conduct under section 4301 of the Code in that, by way of the conduct described
7 in paragraphs 21-38 above, Respondents Southwood and Sempre engaged in acts constituting
8 unprofessional conduct not becoming the professional practice of pharmacy.

9 **FOURTH CAUSE FOR DISCIPLINE**

10 **(Failure to Renew Non-Resident Pharmacy License)**

11 42. Respondent Medipharm Rx Inc. is subject to disciplinary action under section
12 4402(e), in conjunction with California Code of Regulations section 1708.2, in that Respondent
13 Medipharm's license with the Florida Board of Pharmacy (PH21003) was "closed," and expired
14 on February 28, 2007; and Respondent Medipharm's California license expired on January 1,
15 2007, and Respondent Medipharm failed to renew its license and failed to notify the Board of its
16 discontinuance of business under its non-resident pharmacy license no. NRP670, in violation of
17 pharmacy law and as detailed in paragraphs 21-38, above.

18 **FIFTH CAUSE FOR DISCIPLINE**

19 **(Failure to Renew Non-Resident Pharmacy License)**

20 43. Respondent United Prescription Services (UPS) is subject to disciplinary action under
21 section 4402(e), in conjunction with California Code of Regulations section 1708.2, in that
22 Respondent UPS' license with the Florida Board of Pharmacy (PH17181) was "closed," and
23 Respondent UPS' California license expired on May 1, 2005, and Respondent UPS failed to
24 renew its license and failed to notify the Board of its discontinuance of business under its non-
25 resident pharmacy license no. NRP466, in violation of pharmacy law and as detailed in
26 paragraphs 21-38, above.

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1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Failure to Renew Non-Resident Pharmacy License)**

3 44. Respondent Medcenter, Inc. is subject to disciplinary action under section 4402(e), in
4 conjunction with California Code of Regulations section 1708.2, in that Respondent Medcenter's
5 license with the Florida Board of Pharmacy (PH21072) was "delinquent," and expired on
6 February 28, 2009; and Respondent Medcenter's California license expired on October 1, 2007,
7 and Respondent Medcenter failed to renew its license and failed to notify the Board of its
8 discontinuance of business under its non-resident pharmacy license no. NRP752, in violation of
9 pharmacy law and as detailed in paragraphs 21-38, above.

10 **PRAYER**

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

- 13 1. Revoking or suspending Original Wholesale Permit Number WLS 4078, issued to
14 Respondent Southwood Pharmaceutical, Inc.;
- 15 2. Revoking or suspending Pharmacist License Number RPH 25420, issued to
16 Respondent John Sempre;
- 17 3. Revoking or suspending Non-Resident Pharmacy License Number NRP 670, issued
18 to Respondent Medipharm Rx Inc.;
- 19 4. Revoking or suspending Non-Resident Pharmacy License Number NRP 466, issued
20 to United Prescription Services;
- 21 5. Revoking or suspending Non-Resident Pharmacy License Number NRP 752, issued
22 to Medcenter Inc.;
- 23 6. Ordering Respondents Southwood Pharmaceutical, Inc., John Sempre, Medipharm Rx
24 Inc., United Prescription Services and Medcenter Inc. to pay the Board of Pharmacy the
25 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
26 Professions Code section 125.3;

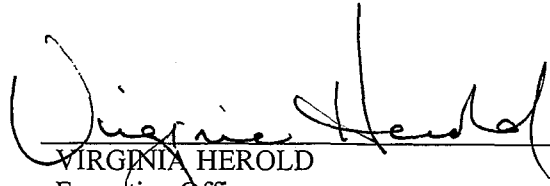
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7. Taking such other and further action as deemed necessary and proper.

DATED: 8/10/10



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

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