STATE AND CONSUMER SERVICES AGENCY DEPARTMENT OF CONSUMER AFFAIRS GRAY DAVIS, GOVERNOR

DEPARTMENT OF CONSUMER AFFAIRS BOARD OF PHARMACY NORTHERN COMPLIANCE COMMITTEE MEETING MINUTES

California State Board of Pharmacy 400 R Street, Suite 4070, Sacramento, CA 95814 Phone (916) 445-5014

Fax (916) 327-6308

DATE:	December 6, 2001
TIME:	9:00 a.m. – 11:07 p.m.
LOCATION:	Department of Consumer Affairs 400 R Street, Suite 4070 Sacramento, CA 95814
BOARD MEMBER PRESENT:	Donald Gubbins, Chairperson Robert Elsner, Board Member Stanley Goldenberg, Board Member
STAFF PRESENT:	Judith K. Nurse, Supervising Inspector Ralph Orlandella, Pharmacy Inspector Linda Kapovich, Enforcement Technician
ALSO PRESENT:	Kisoo Oh, RPH, PIC, ILO Andrew Enerson Curry, Attorney at Law Kiran Harish Patel, RPH, former PIC Irwin David Chow, Jr., RPH Susan Mitri, RPH Richard Martland, Attorney at Law Diana Chun, Pharmacy Development Manager Thang Duc Bui, RPH, PIC Satinderjit S. Sandhu, RPH, former PIC Alfred O. Cole, RPH Shiunn-Li Robert Song, RPH, PIC Mitchell Olejko, Attorney at Law Alice Haynes, Vice President of Pharmacy Gregg S. Aspacher, RPH, PIC David Shayman, RPH Elaine Chan, Owner
CALL TO ORDER	

Northern Compliance Committee December 6, 2001, Page 1 of 13 Chairperson Donald Gubbins called the meeting of the Northern Compliance Committee to order at 9:00 a.m.

A. APPEARANCES REQUIRED

1. Reid Bell RPH 22008, PIC CI 1997 15630

Randall Lewis Felkel RPH 29451, former PIC

Model Pharmacy Folsom, CA PHY 37032

William Brent Cowley RPH 41504, PIC

Rite Aid #6266 Folsom, CA PHY 43773

Reid Bell, Randall Lewis Felkel, Model Drug, William Brent Cowley, and Rite Aid #6266 are requested to appear at the Northern Compliance meeting as the result of an investigation that revealed that Model Pharmacy did employ a registered drug addict thus compromising the safety and security of dangerous drugs and controlled substances. Also Reid Bell and Randall Lewis Felkel allowed a non-registered person, without education or training, to act as a pharmacy technician. This unlicensed person was allowed to steal and divert controlled substances from Model Pharmacy for her own use and, by leaving a labeled vial at a home of an acquaintance, allowed confidential patient information to be known by individuals not entitled to that information.

Randall Lewis Felkel allowed the non-registered person to reduce faxed prescription transfers for a family member to writing, a function only a pharmacist can perform. Additionally, there is no indication that Randall Lewis Felkel verified the validity of the prescriptions or refill information.

The investigation also revealed that many Scheduled II controlled substances were dispensed pursuant to triplicate prescriptions written by a prescriber who does not and has not held a DEA registration since 1996. These triplicate prescriptions were clearly marked for dispensing at a specific government facility only and could not be filled at any other pharmacy. Controlled substances and dangerous drugs were also

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Accurate records and required patient information were not maintained and records pertaining to the operation of the pharmacy were not available for inspection.

On July 28, 1998, violation notices were issued to Reid Bell, and Model Drug, for violation of:

- Business and Professions Code, Section 4301 Unprofessional Conduct.
- Code of Federal Regulations 1301.9 Failure to properly screen employees in regard to potential breach of drug security.
- California Code of Regulations, Section 1793.4 Qualifications for Registration as a Pharmacy Technician.
- Code of Federal Regulations, Section 1301.76 Employment with access to controlled substances of a person convicted of a felony related to controlled substances.
- Business and Professions Code section 4081 Records of dangerous drugs and devices kept open for inspection; maintenance of records, current inventory.
- Business and Professions Code section 4332 Misdemeanor: failure or refusal to maintain or produce required drug or device records; willful production of false records.
- Business and Professions Code section 4333 Maintaining prescriptions, other drug records on premises, open to inspection.

On July 28, 1998, violation notices were issued to Randall Lewis Felkel, and Model Drug, for violation of:

- Business and Professions Code section 4301 Unprofessional conduct.
- California Code of Regulations, Section 1793.4 Qualifications for Registration as a Pharmacy Technician
- Business and Professions Code section 4116 Security of dangerous drugs and devices in pharmacy: pharmacist responsibility for individuals on premises; regulations.
- California Code of Regulations, Section 1714 Operational Standards and Security.

On September 13, 2001, a letter of violation was issued to Reid Bell, for violation of:

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- Code of Federal Regulations, Section 1301.76 Employment with access to controlled substances of a person convicted of a felony related to controlled substances.
- Code of Federal Regulations, Section 1306.21 Requirements for a prescription.
- Code of Federal Regulations, Sections 1306.03, Persons entitled to issue prescriptions.
- Code of Federal Regulations, Section 1306.05(a) Manner of issuance of prescriptions.
- Code of Federal Regulations, Section 1306.11 (d) (3) Requirement of prescription.
- Health and Safety Code, Section 11155 Prohibition of physician prescribing, where controlled substance privileges surrendered.
- Heath and Safety Code, Section 11164 (a)(b)(2) Prescriptions for schedule II,III,IV, and V controlled substance: form and content; record of practitioner dispensing schedule II controlled substance.
- California Code of Regulations, Section 1709.1: Failure to perform duties of a Pharmacist-In-Charge by allowing a non-registered individual to act as pharmacy technician.

On September 13, 2001, a letter of violation was issued to Randall Lewis Felkel, for violation of:

- Code of Federal Regulations, Sections 1306.03, Persons entitled to issue prescriptions.
- Code of Federal Regulations, Section 1306.05(a) Manner of issuance of prescriptions.
- Code of Federal Regulations, Sections 1306..11(d)(3) Requirement of prescription.
- Code of Federal Regulations, Section 1306.21 Requirements for a prescription.
- Business and Professions Code section 4063 Refill of prescription for dangerous drug or device; prescriber authorization.
- California Code of Regulations section 1764 Unauthorized disclosure of prescriptions.
- Health and Safety Code, Section 11155 Prohibition of physician prescribing, where controlled substance privileges surrendered.
- Heath and Safety Code, Section 11164 (a)(b)(2) Prescriptions for schedule II,III,IV, and V controlled substance: form and content; record of practitioner dispensing schedule II controlled substance.
- Heath and Safety Code, Section 11158 Prescription required for schedule II, III, IV, or V controlled substance.

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- Health and Safety Code 11366 Maintaining place for unlawfully providing controlled substance.
- Health and Safety Code section 11200 Restrictions on dispensing or refilling; refill of schedule II prescription barred.
- California Code of Regulations, Section 1793.4 Qualification for registration as a pharmacy technician.
- Business and Professions Code, Sections 4115 Pharmacy technician: activities permitted; required supervision; activities limited to pharmacist; registration; requirements for registration; ratios.
- California Code of Regulations, Section 1714 Operational standards and security.
- Business and Professions Code section 4060 No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, or veterinarian, or furnished pursuant to a drug order issued by a physician assistant pursuant to Section 3502.1 or a nurse practitioner pursuant to Section 2836.1.
- Business and Professions Code section 4116 Security of dangerous drugs and devices in pharmacy: pharmacist responsibility for individuals on premises; regulations.
- Business and Professions Code section 4117 Admission to area where narcotics are stored, etc. who may enter.
- Business and Professions Code section 4070 Reduction of oral or electronic prescriptions to writing.
- California Code of Regulations, Section 1716 Variation from a prescription.
- California Code of Regulations, Section 1717 Pharmaceutical practice.
- California Code of Regulations, section 1793.1 Duties of a registered pharmacist; receive a new prescription order orally from a prescriber or other person authorized by law.

This appearance was postponed prior to this meeting of the Northern Compliance Committee, and will be rescheduled for the February 6, 2002, meeting.

> 2. Kisoo Oh RPH 29705, PIC, ILO

CI 2001 21539

Angell's Mill Oaks Pharmacy Ukiah, CA PHY 35011

Andrew Enerson Curry, Attorney at Law

Northern Compliance Committee December 6, 2001, Page 5 of 13 Kisoo Oh, and Angell's Mill Oaks Pharmacy, are requested to appear at the Northern Compliance meeting as the result of an investigation that revealed that Kisoo Oh dispensed propanolol ER 80mg on a prescription calling for Prozac 20mg.

On September 6, 2001, a letter of violation was issued to Kisoo Oh, and Angell's Mill Oaks Pharmacy, for violation of:

- Business and Professions Code section 4301 Unprofessional conduct.
- California Code of Regulations section 1716 Variation from a prescription.

The participants and the committee discussed the circumstances surrounding the violations and what corrective actions have been taken.

M/S/C: Elsner/Gubbins

The committee accepted the appearance of Kisoo Oh, and Angell's Mill Oaks Pharmacy; (a) the matter will be made a part of the record of Kisoo Oh, RPH 29705; (b) the matter will be made a part of the record of Angell's Mill Oaks Pharmacy, PHY 35011. No further action will be taken at this time.

> 3. Andrew Enerson Curry RPH 50213, PIC

CI 1998 16903

Kiran Harish Patel RPH 45324, former PIC

Irwin David Chow, Jr. RPH 26585

Susan Mitri RPH 49526

Rite Aid #5849 Clovis, CA PHY 42735

Richard Martland, Attorney at Law Diana Chun, Pharmacy Development Manager

Andrew Emerson Curry, Kiran Harish Patel, Irwin David Chow, Jr., Susan Mitri, and Rite Aid #5849, are requested to appear at the Northern Compliance meeting as

Northern Compliance Committee December 6, 2001, Page 6 of 13 the result of an investigation that revealed that Kiran Patel dispensed Sular 20mg on an uncertain prescription written for Sumycin 250mg. Appropriate patent consultation would have caught this error. Irwin D. Chow acknowledged receiving the telephonic prescription and reducing it to writing, but did not know who entered it into the pharmacy computer.

On September 5, 2001, a letter of violation was issued to Kiran Patel and Rite Aid #5849, for violation of:

- Business and Professions Code section 4301 Unprofessional conduct.
- California Code of Regulations section 1716 Variation from a prescription.
- California Code of Regulations section 1761 Erroneous or uncertain prescriptions.
- California Code of Regulations section 1707.2 Duty to consult.

On September 5, 2001, a letter of violation was issued to Irwin D Chow, Jr., for violation of;

- Business and Professions Code section 4301 Unprofessional conduct.
- California Code of Regulations section 1716 Variation from a prescription.

Chairperson Donald Gubbins recused himself from this appearance, and left the room.

The participants and the committee discussed the circumstances surrounding the violations and what corrective actions have been taken.

M/S/C: Goldenberg/Elsner

The committee accepted the appearance of Andrew Emerson Curry, Kiran Harish Patel, Irwin David Chow, Jr., Susan Mitri, and Rite Aid #5849; (a) the matter will be made a part of the record of Kiran Harish Patel, RPH 45324; (b) the matter will be made a part of the record of Irwin David Chow, Jr. RPH 26585; (c) the matter will be made a part of the record of Rite Aid #5849, PHY 42735; (d) Rite Aid #5849, PHY 42735, is cited and fined \$1,000, for failure to provide patient consultation as required. No further action will be taken at this time.

4. Corinne Wiswell RPH 33035, PIC CI 1999 19502

Northern Compliance Committee December 6, 2001, Page 7 of 13 Rite Aid #6073 Sacramento, CA PHY 42261

Corinne Wiswell and Rite Aid #6073, are requested to appear at the Northern Compliance meeting as the result of an investigation that revealed that Corinne Wiswell dispensed generic phenytoin on a transferred prescription calling for brand name Dilantin.

On July 13, 2001, letters of violation were issued to Corinne Wiswell and Rite Aid #6073, for violation of:

- Business and Professions Code section 4301 Unprofessional conduct.
- Business and Professions Code section 4073 (e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label.

This appearance was postponed prior to this meeting of the Northern Compliance Committee. This matter will be rescheduled for the January 9, 2002, meeting.

> 5. Thang Duc Bui RPH 46269, PIC

CI 2000 20498

Satinderjit S. Sandhu RPH 39416, former PIC

Alfred O. Cole RPH 23946

Walgreens #2865 Modesto, CA PHY 40529

Thang Duc Bui, Satinderjit S. Sandhu, Alfred O. Cole, and Walgreens #2865, are requested to appear at the Northern Compliance meeting as the result of an investigation that revealed that Alfred O. Cole dispensed Motrin meant for one patient to another patient with a similar name.

Northern Compliance Committee December 6, 2001, Page 8 of 13 On October 11, 2001, letters of violation were issued to Alfred O. Cole, and Walgreens #2865, for violation of:

- Business and Professions Code section 4301 Unprofessional conduct.
- California Code of Regulations section 1764 Unauthorized disclosure of prescriptions.

The participants and the committee discussed the circumstances surrounding the violations and what corrective actions have been taken.

M/S/C: Goldenberg/Elsner

The committee accepted the appearance of Thang Duc Bui, Satinderjit S. Sandhu, Alfred O. Cole, and Walgreens #2865; (a) the matter will be made a part of the record of Alfred O. Cole, RPH 23945; (b) the matter will be made a part of the record of Walgreens #2865, PHY 40529. No further action will be taken at this time.

6. Thomas Clyde Bruerton RPH 29400, PIC CI 2000 20240

Lynn Mina Lee RPH 44383, former PIC

Wing Keung Tse RPH 43974

Longs Pharmacy #319 Oakland, CA PHY 37931

Thomas Clyde Bruerton, Lynn Mina Lee, Wing Keung Tse, Longs Pharmacy #318, are requested to appear at the Northern Compliance meeting as the result of an investigation that revealed that Wing Keung Tse failed to review the patients medication profile prior to dispensing the medication, and also failed to provide patient consultation as required by law.

On July 5, 2001, letters of violation were issued to Wing Keung Tse, Longs Pharmacy #318, for violation of;

• Business and Professions Code section 4301 – Unprofessional conduct.

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- Business and Professions Code section 4077 Dispensing dangerous drug in incorrectly labeled container.
- California Code of Regulations section 1707.2 Duty to consult.
- California Code of Regulations section 1707.3 Prior to consultation as set forth in section 1707.2(a) and (b), a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The re-view shall include screening for severe potential drug therapy problems.

This appearance was postponed prior to this meeting of the Northern Compliance Committee. This matter will be rescheduled for the January 9, 2002, meeting.

> 7. Wiley Ching RPH 30950, PIC

CI 2000 19639

Anthony Wah Hing Hong RPH 30779, former PIC

Vivien W. M. Tseng RPH 32741

Monica Sandra Scheu RPH 43491

Longs Drug Store #56 San Leandro, CA PHY 15560

Wiley Ching, Anthony Wah Hing Hong, Vivien W. M. Tseng, Monica Sandra Scheu, and Longs Drug Store #56, are requested to appear at the Northern Compliance meeting as the result of an investigation that revealed that Monica Sandra Scheu failed to contact the prescribing physician an incomplete prescription prior to dispensing the medication to the patient. Patient consultation was not provided as required by law.

On September 6, 2001, a letter of violation was issued to Longs Drug Store #56, for violation of:

- Business and Professions Code section 4301 Unprofessional conduct.
- California Code of Regulations section 1716 Variation from a prescription.
- California Code of Regulations section 1761 Erroneous or uncertain prescriptions.

Northern Compliance Committee December 6, 2001, Page 10 of 13 • California Code of Regulations section 1707.2 – Duty to consult.

On September 6, 2001, a letter of violation was issued to Monica Sandra Scheu, for violation of:

- Business and Professions Code section 4301 Unprofessional conduct.
- California Code of Regulations section 1716 Variation from a prescription.
- California Code of Regulations section 1761 Erroneous or uncertain prescriptions.

On September 6, 2001, a letter of violation was issued to Anthony Wah Hing Hong, for violation of:

- Business and Professions Code section 4301 Unprofessional conduct.
- California Code of Regulations section 1707.2 Duty to consult.

This case was postponed due to the fact that Vivien W. M. Tseng was in a car accident on her way to the meeting. This appearance will be rescheduled for the January 9, 2002, meeting.

8. Shiunn-Li Robert Song RPH 50203, PIC CI 2000 20824

Ralphs Pharmacy #929 Santa Rosa, CA PHY 44379

Mitchell Olejko, Attorney at Law Alice Haynes, Vice President of Pharmacy

Shiunn-Li Robert Song, and Ralphs Store #929, are requested to appear at the Northern Compliance meeting as the result of an investigation that revealed that Shiunn-Li Robert Song dispensed Bactroban Ointment on a prescription calling for Bacitracin Ophthalmic Ointment. Shiunn-Li Robert Song also failed to provide patient consultation as required by law.

On October 11, 2001, letters of violation were issued to Shiunn-Li Robert Song, and Ralphs Store #929, for violation of:

- Business and Professions Code section 4301 Unprofessional conduct.
- California Code of Regulations section 1716 Variation from a prescription.

Northern Compliance Committee December 6, 2001, Page 11 of 13 • California Code of Regulations section 1707.2 – Duty to consult.

The participants and the committee discussed the circumstances surrounding the violations and what corrective actions have been taken.

M/S/C: Goldenberg/Elsner

The committee accepted the appearance of Shiunn-Li Robert Song, and Ralphs Store #929; (a) the matter will be made a part of the record of Shiunn-Li Robert Song, RPH 50203; (b) the matter will be made a part of the record of Ralphs Store #929, PHY 44379; (c) Shinn-Li Robert Song, RPH 50203, is cited and fined \$500, for failure to provide patient consultation as required. No further action will be taken at this time.

9. Gregg S. Aspacher RPH 43353, PIC CI 1998 17240

David Shayman RPH 22462

Elaine Chan INO

Four Fifty Sutter Pharmacy San Francisco, CA PHY 30976

Gregg S. Aspacher, David Shayman, Elaine Chan, and Four Fifty Sutter Pharmacy, are requested to appear at the Northern Compliance meeting as the result of an investigation that revealed that Four Fifty Sutter Pharmacy dispensed Zithromax with incorrect directions for use. The prescription was written to take one tablet daily, and the directions on the container read take "4 tablets now." However, the pharmacy personnel failed to respond to the board inspector's request for an explanation of this incident.

On May 22, 2000, a violation notice was issued to Four Fifty Sutter Pharmacy, for violation of:

- Business and Professions Code section 4301 (o) Unprofessional conduct.
- Business and Professions Code section 4076 (a)(2) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following: The directions for the use of the drug.

Northern Compliance Committee December 6, 2001, Page 12 of 13 • Business and Professions Code section 4081 (a) - All records of manufacture, sale, acquisition, or disposition of dangerous drugs or devices shall at all times during business hours be open to inspection by authorized officer of the law, and shall be preserved for at least 3 years....

The participants and the committee discussed the circumstances surrounding the violations and what corrective actions have been taken.

M/S/C: Elsner/Goldenberg

The committee accepted the appearance of Gregg S. Aspacher, David Shayman, Elaine Chan, and Four Fifty Sutter Pharmacy; (a) the matter will be made a part of the record of Four Fifty Sutter Pharmacy, PHY 30976; (b) A follow up inspection is ordered within the next 60 days to ensure compliance with all pharmacy laws. No further action will be taken at this time.

There being no additional discussion, the meeting was adjourned at 11:07 p.m.