



California State Board of Pharmacy
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www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA Communication and Public Education Committee

Date: April 12, 2013
Time: 9:30 a.m. – 12:30 p.m.

Contact: Jan Jamison
(916) 574-7957

Place: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Laura Hendricks at (916) 574-7918, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. A quorum of the board may be present at committee meetings. Board members who are not on the committee may observe, but may not participate as a committee member or vote.

Call to Order

9:30 a.m.

1. Discussion on *Joint Forum to Promote Appropriate Prescribing and Dispensing* held February 21 and 22, 2013, and development of related consumer and licensee education materials
2. Update on availability and distribution of:
 - a. Notice to Consumers Poster (as required by 16 California Code of Regulations Section 1707.6)
 - b. Video Display Format -- Notice to Consumers Poster (as required by 16 California Code of Regulations Section 1707.6)
 - c. Notice of Interpreter Availability (as required by 16 California Code of Regulations Section 1707.6)
3. Discussion of Guidelines for Prescription Container Labels developed by the United States Pharmacopeia
4. Results of surveys regarding prescription container labels
 - a. Discussion of consumer surveys regarding prescription container labels
 - b. Discussion of prescription labels in use in California pharmacies
 1. Availability of Audible Prescription Labeling System
5. For Information: Evaluate patient-centered labels by December 2013 as required by California Code of Regulations Section 1707.5(e)
6. Discussion on Research Advisory Panel's Annual Report 2012
7. Discussion on continuing education credits for joint Board of Pharmacy/DEA presentations to pharmacists on preventing drug abuse and diversion
8. Plans for update of the Consumer Fact Sheet on Emergency Contraception in accordance with 16 California Code of Regulations Section 1746
9. Update on *The Script*
10. Update on redesign of the board's website
11. Update on board's consumer education materials
12. Public outreach activities conducted by the board

13. Public comment for items not on the agenda*

**(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Adjournment

12:30 p.m.

Meeting materials will be available from the board's website by April 9, 2013.



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DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: **Date: April 12, 2013**

To: **Communication and Public Education Committee**

Subject: **Agenda Item 1 – Discussion on Joint Forum to Promote Appropriate Prescribing and Dispensing held February 21 and 22, 2013, and development of related consumer and licensee education materials**

The California State Board of Pharmacy and the Medical Board of California sponsored the Joint Forum to Promote Appropriate Prescribing and Dispensing on February 21 and 22, 2013, in South San Francisco. The forum was created in response to the significant and escalating problem of prescription drug abuse.

The goal of the forum was to educate prescribers, dispensers, prosecutors, regulators, members of law enforcement and others about the problem and to offer possible solutions.

The forum was well attended, with 354 in attendance on the first day and 380 in attendance on the second day. The Board of Pharmacy and the Medical Board both offered four hours of CE credits for the first day and six hours of CE credits for the second day.

Keynote speakers included Michael Botticelli, Deputy Director of the White House Office of National Drug Control Policy, and Joseph Rannazzisi, Deputy Assistant Administrator of the Office of Diversion Control, Drug Enforcement Administration. Other speakers and panelists provided further education and discussion surrounding the problem and the importance of cooperation between physicians and pharmacists.

A presentation about CURES, California's prescription drug monitoring program, was given by the Department of Justice. CURES has an important role in the continuing battle against prescription drug abuse, and the DOJ through 2013 proposed legislation is seeking funding for the future support of the program.

Agenda Item 1 Attachments 1 and 2 contain program evaluations of the forum by participants, where the great majority of responses were very positive.

At this Meeting:

The committee will have an opportunity to hear comments from the executive and assistant executive officers of this board and the Medical Board who worked on the Forum; specifically on what worked, and how to proceed in the future. A presentation before the Medical Board's public education committee occurred earlier today.



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DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: April 12, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 2 -- Update on availability and distribution of:

- a. New Notice to Consumers Poster
 - b. Video Display Format – Notice to Consumers
 - c. Notice of Interpreter Availability poster
-

- a. The new Notice to Consumers poster is scheduled to mail to all pharmacies by mid-April. The single poster is now a new size: 18 inches by 24 inches and will fit in a standard-sized poster frame.

Foreign language versions of the Notice to Consumers poster have been printed in six additional languages: Chinese, Tagalog, Korean, Spanish, Russian and Vietnamese. The printed versions of the foreign language posters are 11 inches by 17 inches and can be ordered from the board. The translated posters can also be downloaded from the board's website under the "Publications" tab and printed on 8.5 inch x 11 inch or 11 inch by 17 inch paper.

- b. The video display format of the Notice to Consumers is available in English or Spanish for pharmacies that request it. The video is also available for download from the board's website under the "Publications" tab.
- c. The Notice of Interpreter Availability poster will also be included in the Notice to Consumers mailing. The poster is 8.5 inches by 11 inches and will be available for download from the board's website.

A letter from Executive Officer Herold explaining the regulations for placement and display of the posters will be included with the mailing. **(Agenda Item 2 Attachment)**

The regulations also provide provisions for pharmacies to develop their own video version of the Notice to Consumers poster and the Notice of Interpreter Availability. At the February Board meeting, the board directed that these exemption requests be sent to this committee for action. No requests for waivers have yet been received.



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GOVERNOR EDMUND G. BROWN JR.

Date: April 12, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 3 — Discussion of Guidelines for Prescription Container Labels Developed by the United States Pharmacopeia

Agenda Item 3 Attachment

The United States Pharmacopeia recently completed their recommendations for prescription container labels. A copy of these recommendations are provided in **Agenda Item 3 Attachment**.

During this meeting, one segment of the agenda will start the committee on initiating a review of the patient-centered labeling requirements adopted. Review of the material in USP's guidelines would be one source of information useful for comparison.

It is important to note that these recommendations already closely resemble the board's existing regulation requirements for patient-centered prescription container labels, specifically:

- Organize the prescription label in a patient-centered way. Feature the information patients most often seek out or need to understand about taking the medication safely.
 - Emphasize: directions
 - At the top of the label place: patient's name
 - Drug name (spell out full brand AND generic name)
 - Strength
 - Explicit and clear directions for use in simple language
- Prescription directions should follow a standard format so the patient can expect where to find information.
- Less critical information can be placed elsewhere and in a matter where it will not "supersede" critical patient information, and away from where it can be confused with dosing instructions
- Use language that it is clear, simplified, concise and familiar, and in a standardized manner. Use common terms and full sentences. Do not use unfamiliar words, Latin terms or medical jargon
- Use simplified, standardized sentences that have been developed to ensure ease understanding the directions (by seeking comment from diverse consumers)

- Separate dose from the timing of each dose to clearly explain how many pills to take and specify if there is an appropriate time to take them (morning, noon, evening, bedtime).
- Do not use alphabetic characters for numbers (not in CA's)
- Use standardized directions whenever possible.
- Avoid ambiguous terms such as "take as directed" (not in CA's) unless clear and unambiguous supplemental instructions and counseling are provided
- Include purpose on the label unless patient does not want it, and if used, use "purpose for use" language such as for blood pressure rather than hypertension.
- Limit auxiliary information, and only if evidence based. (not in CA's)
- Use icons only if vetted with the general public (not in CA's)
- Address limited English proficiency.
- Labels should be designed so they are easy to read. Optimize typography by using:
 - High contrast print (black print on white background)
 - Large font sizes in simple, uncondensed fonts in at least 11 point if Arial, or 12 point if Times New Roman)
 - Optimize use of white space between lines (25-30 percent of font size)
 - Horizontal placement of lettering only
 - Sentence case
 - Highlighting, bolding and other typographical cues should enhance patient-centered information, but limit the number of colors used for highlighting
- Address visual impairment (not in CA's)

Regarding addressing limited English speaking/reading patients, USP encourages directions for use in the patient's language as well as in English. Translations should be developed using high quality translation processes (CA's translated directions would fit this criterion).

During this meeting, one segment of the agenda will start the committee on initiating a review of the patient-centered labeling requirements adopted. Review of the material in USP's guidelines would be one source of information useful for comparison.



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GOVERNOR EDMUND G. BROWN JR.

Date: April 12, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 4 — Results of surveys regarding prescription container labels

a. Discussion of Consumer Surveys

The consumer survey soliciting feedback regarding consumer satisfaction with prescription drug container labels was widely distributed. An electronic version of the survey was sent to several consumer groups including AARP, Consumers Union, and California Pan Ethnic Health Network (CPEHN), who in turn distributed it to their ListServe contacts. The survey was also translated into Chinese and Spanish by the board and distributed by CPEHN to the appropriate audiences.

Surveys were also distributed and collected at local Senior Scam Stopper seminars sponsored by the Contractors State License Board.

The board received a total of 1204 completed surveys. Results are summarized in **Agenda Item 4 Attachment 1)**

b. Discussion of prescription labels in use in California pharmacies

As you may remember, for about seven months in 2012, board inspectors collected information about what patient-centered labels were in use in California pharmacies. The results of 767 pharmacy visits are summarized in **Agenda Item 4 Attachment 2.**

In general, nearly 70 percent of the labels in use as found by the board's inspectors are printed in 12-point font, 25 percent use both 10 and 12 point font on the labels, and about 15 percent are printed in 10 point .

b.1. Availability of Audible Prescription Labeling System

Really misplaced on this agenda as item b.1, this item is for information only.

The board recently received information about an audible prescription labeling system. A brochure describing this device is in **Agenda Item 4 Attachment 3.** It is intended as background to the committee to some of the devices that are in use.

Target Market: Customers with vision impairment (low or no vision).

Current Customers: The majority of current customers are independent pharmacies. WalMart, CVS and Kaiser have some available in their mail order pharmacies. The units have been used by the V.A. (nationwide) for ten years.

Cost: No cost to customer
\$1099 for software and \$1.31 per label for pharmacies.



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GOVERNOR EDMUND G. BROWN JR.

Date: April 12, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 5 — Discussion on re-evaluation of patient-centered labels by December 2013 to ensure conformance with regulation 1707.5(e)

A provision promulgated as part of the patient-centered label regulations requires the board to review the requirements for patient-centered regulations prior to December 2013.

At this meeting and over the remaining meetings of this committee this year, the committee will work on this assessment. Information developed by the committee will be referred to the board for action or comment at the next board meeting.

Materials provided in Agenda Items 3 and 4 may assist the committee in initiating this review. The text of the regulation (section 1707.5) follows at the bottom of this memorandum. Also provided in various attachments are:

Agenda 5 Attachment 1: The first board report to the Legislature on the efforts to implement patient-centered labeling requirements

Agenda 5 Attachment 2: Samples of patient-centered labels
Additional samples will be brought to the meeting

1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

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

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

(A) Name of the patient

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

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

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

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in

paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

- (A) Take 1 [insert appropriate dosage form] at bedtime
 - (B) Take 2 [insert appropriate dosage form] at bedtime
 - (C) Take 3 [insert appropriate dosage form] at bedtime
 - (D) Take 1 [insert appropriate dosage form] in the morning
 - (E) Take 2 [insert appropriate dosage form] in the morning
 - (F) Take 3 [insert appropriate dosage form] in the morning
 - (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
 - (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
 - (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
 - (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening
 - (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
 - (L) Take 3 [insert appropriate dosage form] in the morning, 3 insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
 - (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
 - (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
 - (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
 - (P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before taking again. Do not take more than ___ [appropriate dosage form] in one day
- (b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
- (c) Beginning in October 2011 the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
- (d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. If interpretive services in such language are

available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: April 12, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 6 – Discussion on Research Advisory Panel’s Annual Report to the Legislature and Governor for 2011

Agenda 6 Attachment 1

For Information:

Pursuant to Health & Safety Code Sections 11480 & 11481, California Law requires proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II Controlled Substances to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General’s Office.

The Research Advisory Panel primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances used in the study. The panel members evaluate the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of research.

The board has one appointee to this committee, Sheri VanOsdol, PharmD. Dr. VanOsdol is a faculty member at UCSF.



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GOVERNOR EDMUND G. BROWN JR.

Date: April 12, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 7 – Discussion and Possible Approval to Award Continuing Education Credit for Attendees of a Drug Enforcement Administration Conference on Prescription Drug Abuse to Be Held This Spring and Summer

There are three proposals below for which the committee is asked to review. These proposals are aimed at providing important educational information to board licensees and other interested parties, and to provide licensees with CE credit for attending.

Proposal 1:

Over the last two years, the board has hosted several one-day seminars for pharmacists and other interested parties on drug diversion, prescription drug abuse and corresponding responsibility for pharmacists. Our partner in this has been the California Office of the Drug Enforcement Administration.

On dates to be determined later in 2013, board staff hope to again host two or three of these seminars with the Los Angeles DEA office. Board licensees in the regional area will be invited to attend.

The last regional presentation of this kind was held on April 12, 2012, on Drug Security for Pharmacists, for which the board awarded attending pharmacists and pharmacy technicians five hours of continuing education credit.

Board staff requests that the committee recommend to the board to again award five hours of CE credit for pharmacists and pharmacy technicians who attend this meeting. A copy of a draft agenda appears as the last page of this memorandum.

Proposal 2:

The board's executive officer has been advised that in mid-August 2013, the Washington DC headquarters office of the DEA has invited the board to cohost with them four, one-day seminars for pharmacists in California on controlled substances issues, prescription drug abuse, corresponding responsibility and other matters related to curtail drug diversion. This is a return of the original concept for the seminars

outlined in Proposal 1, but using national DEA staff. Initially started in San Diego in 2010, the DEA has provided these seminars across the country in conjunction with the state boards of pharmacy, and upwards of 300 pharmacists have attended each of these presentations.

The dates are August 16 and 17 in San Diego, and August 18 and 19 in San Jose. Additional material will be provided to the board in the near future.

Board staff request that the committee recommend to the board that the board agree to cohost these events (the July meeting is too late to provide adequate advance publicity to encourage attendance) and that five or six hours of CE credit (as determined by the content hours) be provided for these meetings.

Proposal 3:

Periodically, board staff (principally board inspectors, supervising inspectors and the executive officers) provide 1-2 hour presentations to licensees on key Board of Pharmacy issue areas. For example:

- Duties of a pharmacist in charge
- The operations, functions and key priorities of the board's enforcement program
- New pharmacy laws
- E-Pedigree parameters
- Medication errors

The board receives a list of these presentations are typically in this committee's public outreach report.

The staff requests that this committee recommend to the board that the board reaffirms its commitment to this continuation of these presentations and the award of continuing education credit continue to be offered to improve the knowledge of board licensees.

**DEA and Board of Pharmacy Joint Seminar
on Controlled Substances Issues in California**
DRAFT AGENDA

9:30 am Welcome/Orientation
DEA & California Board of Pharmacy

10:00 am Drug Trafficking /Trends in Los Angeles
DEA

11:00 am

Break

11:15 am Controlled Substances Utilization Review and Evaluation System -- CURES
Records, Inquiries and Reports

12:30 pm Lunch

1:30 pm Pharmaceutical Supply Chain Thefts
Reporting and Prevention
Board of Pharmacy

2:00 pm Corresponding Responsibility
Board of Pharmacy & DEA

2:30 pm

Break

3:00 pm Prescription Drug Abuse and Drug Take Back Programs
Board of Pharmacy & DEA

3:15 pm Questions to Panel

4:00 pm

Adjournment



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: April 12, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 8 – Plans for Update of the Consumer Fact Sheet on
Emergency Contraception in accordance with 16 California Code of
Regulations Section 1746

Very recently, the Office of Administrative Law approved the board's rulemaking to update section 1746 regarding a joint protocol with the California Medical Board to authorize pharmacist to provide emergency contraception without a prescription to patients of any age. This regulation will take effect July 1, 2013.

Part of the regulation requires that a fact sheet for patients be developed by the board and made available so that pharmacists can provide it at the time of consultation. Specifically:

1746 (6)(4) The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record by Section 1707.1 of Title 16 of the California Code of Regulations. Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code section 4052.3.(e)

(The full text of the regulation is provided at the back of this memorandum.)

I am pleased to advise that USC School of Pharmacy Professor Katherine Besinque, who was the board's subject matter expert in developing the modified regulation, very recently provided the board with an updated version of a draft fact sheet that can be used by the board for the final version.

This current version of the fact sheet (pre-regulation change) and draft developed by Dr. Besinque are provided. I will bring to the meeting several other EC fact sheets in use for discussion. However, I believe that the factsheet may need to be worked on in the coming weeks and brought to the committee for its final review at the next committee meeting.

Current version of the fact sheet:



Key Facts About Emergency Contraception

Emergency Contraception (EC) is a safe and effective way to prevent pregnancy after sex.

Consider using Emergency Contraception if:

- You didn't use a contraceptive during sex, or
- You think your contraceptive didn't work.

What are Emergency Contraceptive pills?

Emergency Contraceptive pills contain the same medication as regular birth control pills, and help to prevent pregnancy. There are two basic types of Emergency Contraceptive pills:

- Plan B™ progestin-only pills
- High doses of regular oral contraceptive pills.

Don't wait! Take EC as soon as possible.

- It is best to take EC within three days of unprotected sex.
- The sooner you take EC the more effective it is.
- For more information talk to your pharmacist or doctor.

EC is safe and effective.

- Progestin-only pills reduce the risk of pregnancy by 89 percent.*
- Combined estrogen/progestin pills reduce the risk of pregnancy by 75 percent.*
- For regular, long-term use, other contraceptive methods are more effective than EC.
- Emergency Contraceptive pills do not protect against sexually transmitted infections, including HIV/AIDS.

** Pregnancy risk reduction based on one-time use.*

EC won't cause an abortion.

- Emergency Contraceptive pills are NOT the same as RU-486 (the abortion pill).
- Emergency Contraceptive pills are not effective after pregnancy has occurred and cannot interrupt it.

EC won't harm a developing fetus.

- If Emergency Contraceptive pills are taken mistakenly during pregnancy, they will not harm the developing fetus.
- Using Emergency Contraceptive pills will not affect a woman's ability to become pregnant in the future.

Women can keep pills at home in case of an emergency.

- Many women find it convenient to have Emergency Contraceptive pills on hand in case of an emergency.
- Medical providers or your pharmacist can provide Emergency Contraceptive pills before they are needed.

Medical follow-up after taking Emergency Contraceptive pills

- If you don't get a normal period within three weeks, take a pregnancy test.
- It is important to visit your doctor or clinic if you need a regular birth control method or information about preventing sexually transmitted infections, such as HIV/AIDS.



Approved by the California State Board of Pharmacy
Revised July 2004 • Printed by Pharmacy Access Partnership

Draft text for new fact sheet:

Facts About Emergency Contraception

Emergency Contraception (EC) is a safe and effective way to prevent pregnancy after sex.

Consider using Emergency Contraception if:

- You had unprotected sex, or
- You think your contraceptive did not work.

What are Emergency Contraceptive pills?

Emergency Contraceptive pills contain the same medication as regular birth control pills, and help to prevent pregnancy. There are three basic types of EC pills:

- Progestin-only pills (PlanB® One-Step, Next Choice®)
- Ulipristate acetate (ella®)
- High doses of regular oral contraceptive pills

Don't wait! Take EC as soon as possible.

- It is best to take EC as soon as possible; the sooner you take EC the more effective it is.
- It has been shown to be effective for up to 5 days.
- For more information talk to your pharmacist or doctor.

EC is safe and effective.

- Emergency contraception may reduce the risk of pregnancy by up to 89 percent.
- The effectiveness of EC varies based on the type used and when it is taken.
- Emergency Contraception is only recommended as a back-up and should not be used as your primary method of birth control.
- Emergency Contraceptive pills do not protect against sexually transmitted infections, such as HIV/AIDS.

What EC does.

- Emergency Contraceptive pills prevent pregnancy.
- Emergency Contraceptive pills are not effective after pregnancy has occurred and they will not harm the developing fetus.
- Emergency Contraceptive pills are NOT the same as RU-486 (the abortion pill)
- Using EC will not affect a woman's ability to become pregnant in the future.

Follow-up after taking Emergency Contraceptive pills

- If you vomit after taking EC, you may need to take another dose. Contact your pharmacist or your regular healthcare provider immediately.
- If you do not get a normal period within three weeks, take a pregnancy test.
- It is important to visit your doctor or clinic for a regular birth control method and information about preventing sexually transmitted infections.
- Medical providers or your pharmacist can provide EC for future use if needed.

[add the following in box during formatting]

In California, women and men may receive free family planning services through Family PACT based on income.

If you don't have a doctor or clinic, call 1-800-942-1054 to find a Family PACT provider near you.

Under the Affordable Care Act (ACA), EC may be covered with a prescription.

Revised February 2013

Approved by the Office of Administrative Law 3/13/13
Filed with the Secretary of State 3/13/13
Effective Date 7/1/13

§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052.3(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and communicate the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) after unprotected intercourse.

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. For other options for EC, consult with your health care provider.

Please follow up with your health care provider after the use of EC.

(4) The pharmacist shall provide a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

| <i>Brand</i> | <i>Dose</i> | <i>Ethinyl Estradiol per dose (mcg)</i> | |
|----------------------------|-------------|---|-------------------------|
| <i>One Tablet Regimens</i> | | | |
| Plan B™ One-Step | 1 tablet | 0 | 1.5mg levonorgestrel |
| ella™ | 1 tablet | 0 | 30mg ulipristal |
| Levonorgestrel | 1 tablet | 0 | 1.5mg levonorgestrel |

| <i>Two Tablet Regimens</i> | | | |
|----------------------------|--|---|---|
| Next Choice™ | 2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later | 0 | Each tablet is 0.75 mg levonorgestrel |
| Levonorgestrel | 2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later | 0 | Each tablet is 0.75 mg levonorgestrel |

Oral Contraceptive Pills

| <i>Brand</i> | <i>Tablets per Dose (two doses 12 hours apart*)</i> | <i>Ethinyl Estradiol per dose (mcg)</i> | <i>Levonorgestrel per dose (mg)*</i> |
|--------------|---|---|--|
| Allesse | 5 pink tablets | 100 | 0.50 |
| Aviane | 5 orange tablets | 100 | 0.50 |
| Levlen | 4 light-orange tablets | 120 | 0.60 |
| Levlite | 5 pink tablets | 100 | 0.50 |
| Levora | 4 white tablets | 120 | 0.60 |
| Lo/Ovral | 4 white tablets | 120 | 0.50 |
| Low-Ogestrel | 4 white tablets | 120 | 0.60 |
| Nordette | 4 light-orange tablets | 120 | 0.60 |
| Ogestrel | 2 white tablets | 100 | 0.50 |
| Ovral | 2 white tablets | 100 | 0.50 |
| Tri-Levlen | 4 yellow tablets | 100 | 0.50 |
| Triphasil | 4 yellow tablets | 120 | 0.50 |
| Trivora | 4 pink tablets | 120 | 0.50 |
| Ovrette | 20 yellow tablets | 0 | 0.75 |

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

| <i>Non-Prescription Drugs</i> | <i>Dose</i> | <i>Timing of Administration</i> |
|---|---|---|
| Meclizine hydrochloride (Dramamine II, Bonine) | One or two 25 mg tablets | 1 hour before first EC dose; Repeat if needed in 24 hours |
| Diphenhydramine hydrochloride (Benadryl) | One or two 25 mg tablets or capsules | 1 hour before first EC dose; repeat as needed every 4-6 hours |
| Dimenhydrinate (Dramamine) | One or two 50 mg tablets or 4-8 teaspoons liquid | 30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours |
| Cyclizine hydrochloride (Marezine) | One 50 mg tablet | 30 minutes before first EC dose; repeat as needed every 4-6 hours |

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: April 12, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 9 – Update on *The Script*

The most recent issue of *The Script* was released in March 2013. This issue included an article on the FDA Guidelines for Medication Guide Distribution and detailed the compliance guidelines for electronically transmitted prescription. Also included in this issue were answers to frequently asked questions, best practices and a summary of disciplinary actions taken.

The next issue of the newsletter is currently under development. It will include information on recent changes in pharmacy law as well as provide information on the Joint Forum to Promote Appropriate Prescribing and Dispensing, which was co-hosted by the Medical Board of California on February 21 and 22 in South San Francisco. The issue will also feature an article on the CURES system. We hope to have this next issue released in early July 2013.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: April 5, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 10 – Update on Redesign of Board’s Website

As time permits, staff is continuing work on the new design for the Board website. The new site will provide a more contemporary design and color palette and be consistent with the look and feel of the Governor’s office website and those of other DCA boards and bureaus.

New site architecture is also being designed to provide a more intuitive and easy-to-navigate user experience so licensees, applicants and consumers can quickly find the information they need. A more intuitive navigation should also cut down on unnecessary questions and calls to the board.

Website content is also being reviewed and updated or removed if outdated.

We hope to have much of this work completed and have the change to the new web site design and format to coincide with our transition to the new BreEZe computer system, which is also a web based system.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: April 5, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 11 – Update on Consumer Education Materials

Staff is continuing to evaluate the board's existing consumer education materials and fact sheets to identify those that should be updated or removed from the board's library. The attached chart identifies the fact sheets that are most frequently downloaded and will provide a strategy for prioritizing updates. **(Attachment 1)**

Priority has been given to the production of new consumer brochures that address urgent and relevant public pharmaceutical issues. The following new consumer brochures have been written and are in the design and print stage of production:

1. *Prescription Drug Abuse*
2. *Prescription Drug Abuse Among Teens*
3. *Counterfeit Drugs*
4. *Purchasing Pet Meds Safely from Online Pharmacies*

Several more topics have been identified and brochures will be developed on an ongoing basis.

All new brochures will be designed with a uniform, tri-fold layout to support the board's branding efforts. **(Attachment 2)**



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Date: April 12, 2013

To: Communication and Public Education Committee

Subject: Agenda Item 12 – Public Outreach Activities Conducted by the Board

State government continues to be subject to a travel freeze that restricts all but the most essential travel. The Department of Consumer Affairs must still preapprove all travel not involving enforcement issues where a travel claim will be submitted. This has restricted board operations in all areas, including public and licensee outreach.

Recent public and licensee outreach activities performed that have not been reported to the board for fiscal year 2012/13 include:

- November 8: Inspector Bob Kazebee provided a presentation to pharmacists on the duties and responsibilities of being a pharmacist-in-charge to 70 pharmacists at a CE event in
- November 16: Inspector De' Bora White provided a presentation to pharmacists on the duties and responsibilities of being a pharmacist-in-charge at a CE event hosted by the UFCW.
- February 21 and 22: Board cohosts with the Medical Board a forum on Appropriate Prescribing and Dispensing of Controlled Substances in San Francisco. Nearly 400 people attend each day.
- February 25: Supervising Inspector Dang provided a presentation on the duties and responsibilities of being a pharmacist-in-charge to students at Western University School of Pharmacy
- Supervising Inspector Judi Nurse provided a presentation to Loma Linda University School of Pharmacy Students on the Board of Pharmacy
- March 12: Executive Officer Herold provided information on the board's enforcement program and new pharmacy laws to over 50 pharmacy students at Touro School of Pharmacy
- March 18: Executive Officer Herold provided information on the board's enforcement program and new pharmacy laws to 100 attendees at the annual meeting of the California Pharmacist Association.

- March 20: Executive Officer Herold provided a webinar to a large number of manufacturers, wholesalers and pharmacies regarding implementation issues for e-pedigree
- March 26: Executive Officer Herold provided information about California regulation of those who dispense, store, ship and sell prescription drugs and devices in California to a group of travelers from China at the request of the Department of Consumer Affairs
- March 26: Executive Officer Herold provided information on the board's enforcement program and new pharmacy laws to 60 attendees at California Northstate School of Pharmacy

Agenda Item I

Attachment I



California Medical and Pharmacy Boards' Joint Forum to Promote Appropriate Prescribing & Dispensing



Program Evaluation Data – Day 1 – Thursday, February 21, 2013

Please rate your level of agreement for the program meeting the following objectives:

| Objective | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|---|-------------------|----------|---------|--------------|----------------|
| To educate participants in the problems created by overprescribing narcotics, addiction, and diversion of prescription drugs. | 6 | 1 | 5 | 114 (35%) | 196 (61%) |
| To inform participants of the nature of drug diversion – how legitimate patients' medications are diverted to illegitimate use. | 5 | 2 | 10 | 127 (39%) | 180 (56%) |
| To provide tools to physicians and pharmacists on how to spot problematic patients and prescriptions. | 7 | 4 | 37 | 136 (44%) | 126 (41%) |
| To inform participants of resources available to physicians who may have patients who are addicts. | 12 | 15 | 56 | 129 (40%) | 107 (34%) |
| To inform participants of the tools available from state and federal regulatory agencies | 7 | 9 | 40 | 145 (46%) | 113 (36%) |

Please rate your level of agreement with the following statements:

| | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|---|-------------------|-------------|---------|--------------|----------------|
| This activity was commercially biased. | 219 (69%) | 63 (20%) | 13 | 8 | 16 |
| I gained knowledge from this activity. | 2 | 1 | 13 | 140 (43%) | 169 (52%) |
| I will apply what I learned in my practice. | 1 | 2 | 38 | 146 (45%) | 135 (41%) |
| What I learned will change my practice. | 3 | 6 | 102 | 124 (40%) | 74 (24%) |

Please indicate whether the speaker(s) was/were effective and enhanced your knowledge base.

| Speakers | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|-----------------------|-------------------|----------|---------|--------------|----------------|
| Michael P. Botticelli | 2 | 3 | 35 | 153 (48%) | 124 (39%) |

| | | | | | |
|-------------------------------|----------|----------|-----------|----------------------------|----------------------------|
| Joseph Rannazzisi | 7 | 6 | 15 | 69 (22%) | 221 (69%) |
| Laura Meyers and Ruth Morentz | 5 | 5 | 40 | 131 (48%) | 92 (34%) |

Agenda Item 1

Attachment 2



California Medical and Pharmacy Boards' Joint Forum to Promote Appropriate Prescribing & Dispensing



Program Evaluation Data – Day 2 – Friday, February 22, 2013

Please rate your level of agreement for the program meeting the following objectives:

| Objective | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|---|-------------------|----------|---------|--------------|----------------|
| To provide tools to physicians and pharmacists on how to spot problematic patients and prescriptions. | 3 | 4 | 13 | 156 (47%) | 156 (47%) |
| To inform participants of resources available to physicians who may have patients who are addicts. | 9 | 20 | 38 | 149 (45%) | 114 (35%) |
| To educate participants in the use of the California CURES program. | 3 | 14 | 0 | 135 (41%) | 180 (54%) |
| To educate participants of the penalties related to improper prescribing and dispensing of controlled substances. | 3 | 10 | 31 | 158 (49%) | 120 (37%) |
| To inform participants of the tools available from state and federal regulatory agencies. | 4 | 10 | 51 | 148 (46%) | 109 (34%) |
| To inform and encourage cooperation and communication between physicians and pharmacists. | 4 | 1 | 11 | 131 (39%) | 185 (56%) |
| To inform participants in how they can become involved in the public policy discussions. | 5 | 21 | 66 | 127 (42%) | 82 (27%) |

Please rate your level of agreement with the following statements:

| | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|---|-------------------|-------------|---------|--------------|----------------|
| This activity was commercially biased. | 242 (72%) | 62 (19%) | 12 | 7 | 11 |
| I gained knowledge from this activity. | 2 | 2 | 12 | 148 (44%) | 169 (51%) |
| I will apply what I learned in my practice. | 2 | 2 | 34 | 153 (46%) | 139 (42%) |
| What I learned will change my practice. | 4 | 6 | 62 | 155 (47%) | 100 (31%) |

Please indicate whether the speaker(s) was/were effective and enhanced your knowledge base.

| Speakers | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|--|-------------------|----------|---------|--------------|----------------|
| Cesar A. Aristeiguieta, M.D. | 5 | 5 | 20 | 114 (36%) | 177 (55%) |
| Judi Nurse, Pharm.D. | 5 | 2 | 35 | 145 (45%) | 134 (42%) |
| Darlene Fujimoto, Pharm.D. | 5 | 3 | 21 | 154 (48%) | 137 (43%) |
| David Greenberg, M.D. | 9 | 1 | 24 | 123 (38%) | 167 (52%) |
| Michel Sucher, M.D. | 3 | 0 | 25 | 54 (47%) | 32 (28%) |
| Kevin Barnard | 7 | 5 | 39 | 146 (48%) | 107 (35%) |
| Panel of Medical and Pharmacy Experts | 4 | 3 | 40 | 143 (44%) | 135 (42%) |
| Darlene Fujimoto, Pharm.D. / Gregory Polston, M.D. | 6 | 3 | 32 | 144 (48%) | 128 (42%) |
| Mike Small | 5 | 1 | 34 | 133 (43%) | 136 (44%) |
| Panel of Experts from Federal, State, and Local Law Enforcement/Prosecutors | 5 | 3 | 35 | 133 (43%) | 132 (43%) |
| Panel of Regulators and Policy Makers | 3 | 5 | 25 | 112 (46%) | 99 (41%) |

Agenda Item 3

Attachment

Add the following:

◊ (17) PRESCRIPTION CONTAINER LABELING

INTRODUCTION

Medication misuse has resulted in more than 1 million adverse drug events per year in the United States. Patients' best source (and often only source) of information regarding the medications they have been prescribed is on the prescription container label. Although other written information and oral counseling sometimes may be available, the prescription container label must fulfill the professional obligations of the prescriber and pharmacist. These obligations include giving the patient the most essential information needed to understand how to safely and appropriately use the medication and to adhere to the prescribed medication regimen.

Inadequate understanding of prescription directions for use and auxiliary information on dispensed containers is widespread. Studies have found that 46% of patients misunderstood one or more dosage instructions, and 56% misunderstood one or more auxiliary warnings. The problem of misunderstanding is particularly troublesome in patients with low or marginal literacy and in patients receiving multiple medications that are scheduled for administration using unnecessarily complex, nonstandardized time periods. In one study, patients with low literacy were 34 times more likely to misinterpret prescription medication warning labels. However, even patients with adequate literacy often misunderstand common prescription directions and warnings. In addition, there is great variability in the actual auxiliary warning and supplemental instructional information applied by individual practitioners to the same prescription. The specific evidence to support a given auxiliary statement often is unclear, and patients often ignore such information. The essential need for, and benefit of, auxiliary label information (both text and icons) in improving patient understanding about safe and appropriate use of their medications vs. explicit simplified language alone require further study.

Lack of universal standards for labeling on dispensed prescription containers is a root cause for patient misunderstanding, nonadherence, and medication errors. On May 18, 2007, the USP Safe Medication Use Expert Committee established an Advisory Panel to: 1) determine optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription medication instructions and 2) create universal prescription label standards for format/appearance and content/language.

In November 2009, the Health Literacy and Prescription Container Labeling Advisory Panel presented its recommendations to the Safe Medication Use Expert Committee, which then requested that USP develop patient-centered label standards for the format, appearance, content, and language of prescription medication instructions to promote patient understanding. These recommendations form the basis of this general chapter.

Note—These standards do not apply when a prescription drug will be administered to a patient by licensed personnel who are acting within their scope of practice.

PRESCRIPTION CONTAINER LABEL STANDARDS TO PROMOTE PATIENT UNDERSTANDING

Organize the prescription label in a patient-centered manner: Information shall be organized in a way that best reflects how most patients seek out and understand medication instructions. Prescription container labeling should feature only the most important patient information needed for safe and effective understanding and use.

Emphasize instructions and other information important to patients: Prominently display information that is critical for patients' safe and effective use of the medicine. At the top of the label specify the patient's name, drug name (spell out full generic and brand name) and strength, and explicit clear directions for use in simple language.

The prescription directions should follow a standard format so the patient can expect that each element will be in a regimented order each time a prescription is received.

Other less critical but important content (e.g., pharmacy name and phone number, prescriber name, fill date, refill information, expiration date, prescription number, drug quantity, physical description, and evidence-based auxiliary information) should not supersede critical patient information. Such less critical information should be placed away from dosing instructions (e.g., at the bottom of the label or in another less prominent location) because it distracts patients, which can impair their recognition and understanding.

Simplify language: Language on the label should be clear, simplified, concise, and familiar, and should be used in a standardized manner. Only common terms and sentences should be used. Do not use unfamiliar words (including Latin terms) or medical jargon.

Use of readability formulas and software is not recommended to simplify short excerpts of text like those on prescription labels. Instead, use simplified, standardized sentences that have been developed to ensure ease of understanding the instructions correctly (by seeking feedback from samples of diverse consumers).

Give explicit instructions: Instructions for use (i.e., the SIG or signatur) should clearly separate the dose itself from the timing of each dose in order to explicitly convey the number of dosage units to be taken and when (e.g., specific time periods each day such as morning, noon, evening, and bedtime). Instructions shall include specifics on time periods. Do not use alphabetic characters for numbers. For example, write "Take 2 tablets in the morning and 2 tablets in the evening" rather than "Take two tablets twice daily".

Whenever available, use standardized directions (e.g., write "Take 1 tablet in the morning and 1 tablet in the evening" if the prescription reads b.i.d.). Vague instructions based on dosing intervals such as twice daily or 3 times daily, or hourly intervals such as every 12 hours, generally should be avoided because such instructions are implicit rather than explicit, they may involve numeracy skills, and patient interpretation may vary from prescriber intent. Although instructions that use specific hourly times (e.g., 8 a.m. and 10 p.m.) may seem to be more easily understood than implicit vague instructions, recommending dosing by precise hours of the day is less readily understood and may present greater adherence issues due to individual lifestyle patterns, e.g., shift work, than more general time frames such as in the morning, in the evening, after breakfast, with lunch, or at bedtime. Consistent use of the same terms should help avoid patient confusion.

Ambiguous directions such as "take as directed" should be avoided unless clear and unambiguous supplemental instructions and counseling are provided (e.g., directions for use that will not fit on the prescription container label). A clear statement referring the patient to such supplemental materials should be included on the container label.

Include purpose for use: If the purpose of the medication is included on the prescription, it should be included on the prescription container label unless the patient prefers that it not appear. Always ask patients their preference when prescriptions are submitted for filling. Confidentiality and FDA approval for intended use (e.g., labeled vs. off-label use) may limit inclusion of the purpose on labels. Current evidence supports inclusion of purpose-for-use language in clear, simple terms (e.g., "for high blood pressure" rather than "for hypertension").

Limit auxiliary information: Auxiliary information on the prescription container label should be evidence-based in simple explicit language that is minimized to avoid distracting patients with nonessential information. Most patients, particularly those with low literacy, pay little attention to auxiliary information. The information should be presented in a standardized manner and should be critical for patient understanding and safe medication use (e.g., warnings and critical administration alerts). Icons are frequently misunderstood by patients. In addition, icons that provide abstract imagery for messages that are difficult to visually depict may be ineffective at improving understanding compared with simplified text alone. Use only icons for which there is adequate evidence, through consumer testing, that they improve patient understanding about correct use. Evidence-based auxiliary information, both text and icons, should be standardized so that it is applied consistently and does not depend on individual practitioner choice.

Address limited English proficiency: Whenever possible, the directions for use on a prescription container label should be provided in the patient's preferred language. Otherwise there is a risk of misinterpretation of instructions by patients with limited English proficiency, which could lead to medication errors and adverse health outcomes. Additionally, whenever possible, directions for use should appear in English as well, to facilitate counseling; the drug name shall be in English so that emergency personnel and other intermediaries can have quick access to the information.

Translations of prescription medication labels should be produced using a high-quality translation process. An example of a high-quality translation process is:

- Translation by a trained translator who is a native speaker of the target language
- Review of the translation by a second trained translator and reconciliation of any differences
- Review of the translation by a pharmacist who is a native speaker of the target language and reconciliation of any differences
- Testing of comprehension with target audience

If a high-quality translation process cannot be provided, labels should be printed in English and trained interpreter services used whenever possible to ensure patient comprehension. The use of computer-generated translations should be limited to programs with demonstrated quality because dosage instructions can be inconsistent and potentially hazard-

ous. Standardized translated instructions and technology advances are needed to ensure the accuracy and safety of prescription container labeling for patients with low English proficiency.

Improve readability: Labels should be designed and formatted so they are easy to read. Currently no strong evidence supports the superiority in legibility of serif vs. sans serif typefaces, so simple uncondensed fonts of either type can be used.

Optimize typography by using the following techniques:

- High-contrast print (e.g., black print on white background).
- Simple, uncondensed familiar fonts with sufficient space within letters and between letters (e.g., Times Roman or Arial).
- Sentence case (i.e., punctuated like a sentence in English: initial capital followed by lower-case words except proper nouns).
- Large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information. Note that point size is not the actual size of the letter, so 2 fonts with the same nominal point size can have different actual letter sizes. X-height, the height of the lower-case x in typeface, has been used as a more accurate indicator of apparent size than point size. For example, for a given point size, the x-height and apparent size of Arial are actually bigger than those for Times Roman. Do not use type smaller than 10-point Times Roman or equivalent size of another font. Older adults, in particular, have difficulty reading small print.
- Adequate white space between lines of text (25%–30% of the point size).
- White space to distinguish sections on the label such as directions for use vs. pharmacy information.
- Horizontal text only.

Other measures that can also improve readability:

- If possible, minimize the need to turn the container in order to read lines of text.
- Never truncate or abbreviate critical information.
- Highlighting, bolding, and other typographical cues should preserve readability (e.g., high-contrast print and light color for highlighting) and should emphasize patient-centric information or information that facilitates adherence (e.g., refill ordering).
- Limit the number of colors used for highlighting (e.g., no more than one or two).
- Use of separate lines to distinguish when each dose should be taken.

Address visual impairment:

- Provide alternative access for visually impaired patients (e.g., tactile, auditory, or enhanced visual systems that may employ advanced mechanics of assistive technology).

Agenda Item 4

Attachment I

D

**California State Board of Pharmacy
Patient-Centered Prescription Label Survey**

Objective

To secure public comments from California consumers regarding the new patient-centered prescription labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007).

Methodology

The consumer survey soliciting feedback regarding the readability of the new prescription drug container labels was widely distributed. An electronic version of the survey was sent to several consumer groups, who in turn distributed the survey to their ListServe contacts. The survey was also translated into Chinese and Spanish and distributed by The California Pan Ethnic Health Network (CPEHN) to the appropriate audiences. Surveys were also collected at five local Senior Scam Stopper seminars sponsored by the Contractors State Licensing Board, which are public outreach events, and a Senior Health Fair in Hayward,.

Results

A total of 1204 surveys were returned. Respondents did not always provide answers to all of the questions. Results are summarized below:

Responses to Yes/No Questions

English: 1142 Surveys Received

| | YES | NO |
|--|------------|-----------|
| 1. Are your prescription container labels easy to read? | 693 (58%) | 502 (42%) |
| 2. Are the directions for taking the medicine easy to understand? | 245 (20%) | 95 (80%) |
| 3. Do you know why you take each of your medicines? | 1049 (87%) | 149 (12%) |
| 4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)? | 963 (80%) | 232 (19%) |

Chinese: 46 Surveys Received

| | YES | NO |
|--|------------|-----------|
| 1. Are your prescription container labels easy to read? | 40 (87%) | 5 (10%) |
| 2. Are the directions for taking the medicine easy to understand? | 45 (98%) | 1 (.02%) |
| 3. Do you know why you take each of your medicines? | 42 (91%) | 4 (.09%) |
| 4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)? | 30 (65%) | 4 (.09%) |

Spanish: 16 Surveys Receive

| | YES | NO |
|--|------------|-----------|
| 1. Are your prescription container labels easy to read? | 6 (38%) | 10 (62%) |
| 2. Are the directions for taking the medicine easy to understand? | 7 (44%) | 9 (56%) |
| 3. Do you know why you take each of your medicines? | 7 (44%) | 9 (56%) |
| 4. Would you like the general reason why you take the medicine to appear on the label (for pain, for infection, etc.)? | 16 (100%) | 0 |

Top responses to open-ended questions:

When asked what information on the label was most important, the top responses were:

1. Directions for use/clear dosing instructions: 539 of 1098 responses = 49%
2. Name of drug (including generic and brand name): 403 of 1098 responses = 36%
3. Side effects/warnings/interactions/contraindications: 68 of 1098 responses = 6%

When asked what changes would make the labels better, the top responses to this open-ended question was:

1. Larger font: 318 of 1180 responses = 26%
2. State purpose for taking med: 84 of 1180 responses = 7%
3. Include brand name as well as generic name: 52 of 1180 responses = 4%

When asked how the information could be improved:

1. Include clear directions/dosing instructions: 123 of 574 responses = 21%
2. Larger font: 43 of 574 = 7%
3. Include purpose for taking the med: 27 of 574 = 4%

Agenda Item 4

Attachment 2

Summary

Patient-Centered Labeling Inspections

DATE: April - August 2012

This survey is intended to be used during inspections of all pharmacies. Unless otherwise indicated, please use tally marks. Sections 1-4 should always be completed. Section 5 will only be used if the pharmacy is compliant and indicated as such in section 4.

| | | |
|----------|------------------------------|------------|
| 1 | Number of Inspections | 767 |
|----------|------------------------------|------------|

| | | | | |
|----------|---|--------------------|------------------|---------------|
| 2 | Patient-Centered Label (B&P 4076[a] & CCR 1707.5[a][1][A] - [D]) | | | |
| | | Chain Store | Community | Clinic |
| | Compliant | 355 | 339 | 1 |
| | Noncompliant | 13 | 67 | 7 |
| | Corrections issued | 13 | 49 | 7 |

| | | | | |
|----------|---|--------------------|------------------|---------------|
| 3 | The label is usually printed in... | Chain Store | Community | Clinic |
| | 10-point font is the default | 40 | 73 | 0 |
| | 12-point font is the default | 280 | 161 | 1 |
| | Both 10-point & 12-point font appear on the label | 47 | 138 | 0 |

Please tally the number in sections 2 and 3 of the survey. This survey is designed to measure compliance with the patient-centered labeling requirements (section 2). Section 3 is designed to identify if pharmacies are defaulting to the larger or smaller font, or using a combination of sizes on the patient-centered elements.

| | | | | |
|----------|--|--------------------|------------------|---------------|
| 4 | Interpretative Services (CCR 1707.5[d]) | | | |
| | | Chain Store | Community | Clinic |
| | Compliant (all 12 languages available) | 349 | 253 | 0 |
| | Noncompliant | 23 | 150 | 1 |
| | Corrections issued | 23 | 146 | 1 |

| | | | | |
|----------|--|--------------------|------------------|---------------|
| 5 | If compliant, interpretative services provided by | Chain Store | Community | Clinic |
| | Staff only | 17 | 2 | 0 |
| | Telephone (e.g. language line) | 68 | 51 | 0 |
| | Combination of staff and telephone | 260 | 199 | 43 |
| | Other, please specify | 0 | 1 | 0 |

Please tally the number of pharmacies compliant and non-compliant in Section 4. Complete Section 5 section only if the pharmacy is compliant with the interpretative services provisions.

Other: Internal system with video conference - UC Davis

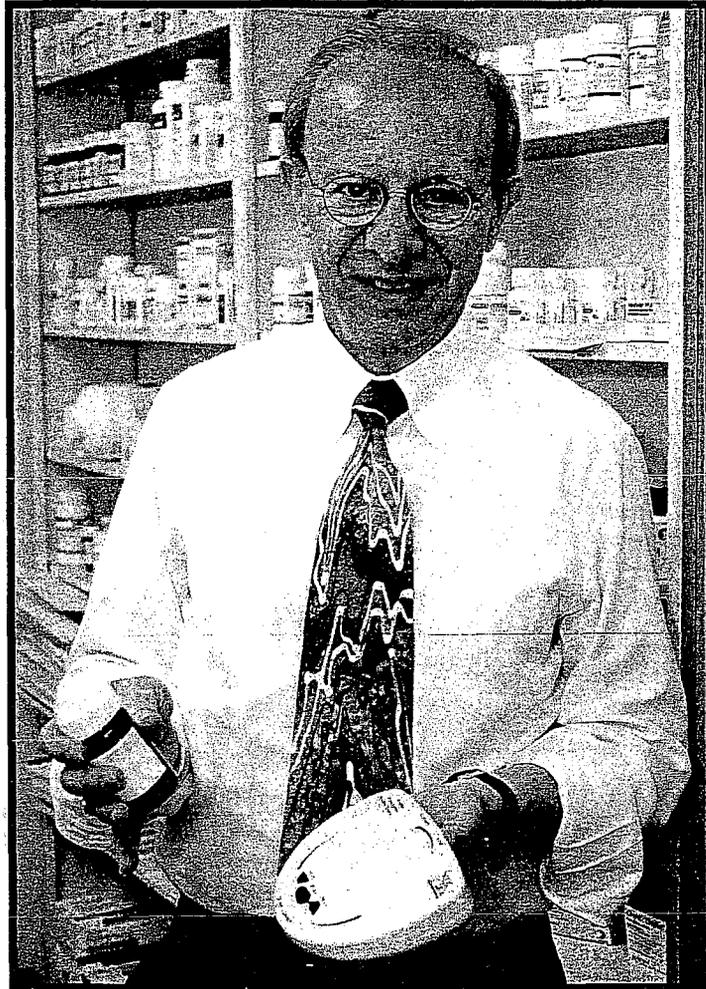
Agenda Item 4

Attachment 3

Attachment E



Audible Prescription Labeling System



Pharmacy Information

What Is ScripTalk® Station?

ScripTalk® Station is an Audible Prescription Labeling System. It provides those who cannot read their prescription labels a safe and easy way to manage their own medication regimen.

Some of your patients who might benefit from this include those with:

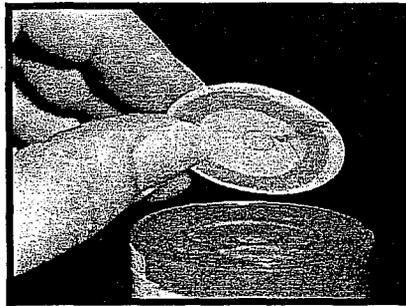
- Blindness or Vision Impairment due to Macular Degeneration, Glaucoma, Cataracts, Diabetic Retinopathy, Retinitis Pigmentosa, etc.;
- Reading Difficulties such as Dyslexia or Illiteracy; or
- The elderly or anyone having difficulty reading small print.

With their own reader units, at the push of a button, patients are able to hear a natural sounding voice speak all of the printed label information including:

- Patient Name
- Drug Name
- Dosage & Instructions
- Warnings & Precautions
- Pharmacy Information
- Doctor Name
- Prescription Number and Date
- Patient Education Monographs

How Does ScripTalk Work In the Pharmacy?

Each pharmacy is equipped with a ScripTalk® Programming unit, ScripTalk® Interface Software, and RFID Talking Labels. A ScripTalk® Printer is optional for high volume operations. Three simple steps allow you to provide vital information and access to your patients. After filling the prescription in normal procedure:



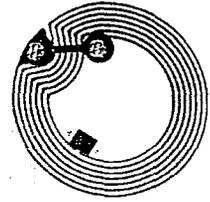
- 1 - Apply a Talking Label to the prescription container and place on top of the ScripTalk® Station programming unit.
- 2 - Encode the RFID tag via the ScripTalk® Interface Software.
- 3 - Verify data transfer and deliver to patient.



What Is the Technology Behind ScripTalk®?

The Label

A special Talking Label stores all the prescription information in a paper-thin, permanent label. The technology is called Radio Frequency Identification, or RFID. Combined with RFID, the ScripTalk Station units use text-to-speech, or TTS, technologies to provide an effective method for providing prescription information to the patient. The small and flexible labels can be placed onto any type or size of prescription container (bottle, box, tube, vial, etc.).



Embedded within the label are a thin antennae and a microchip that stores all the necessary patient and drug information.

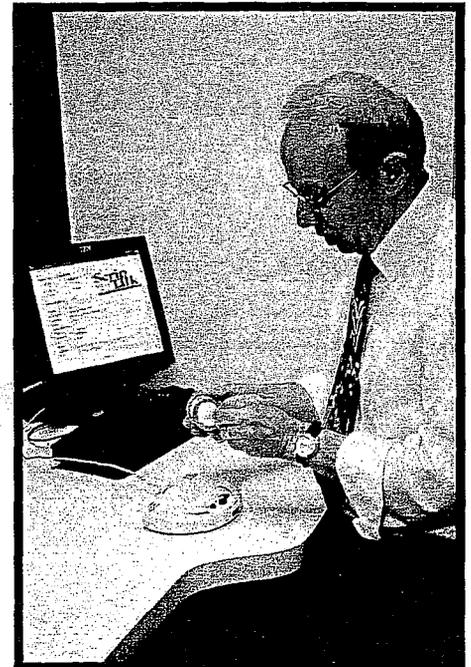
The Software

The ScripTalk® Interface Software is a Windows XP-based program. It easily integrates with a pharmacy's existing software and allows for immediate dispensing and programming of labels.

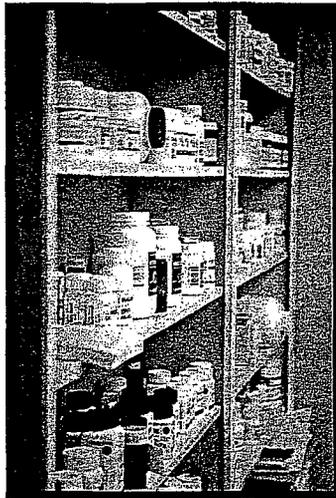
The software can communicate and program Labels via a USB or Serial (RS232) connection.

Patient or prescription specific information can be imported from the pharmacy system, pasted, or hand-entered directly into the data fields. Patient Education Monographs and warning data (provided by First DataBank) can also be loaded directly onto the label.

ScripTalk® Station can program labels in multiple languages and over-the-counter drugs can be supplied with a Talking Label as well.



Value For the Pharmacy



Safety

ScripTalk[®] Station can help to reduce medication errors and adverse drug reactions. It can also increase medication adherence. By providing accessibility to prescription labels through ScripTalk[®], you will be proactive in preventing life-threatening or fatal injuries caused by patient dosing errors. Your patients can correctly identify and take medications as prescribed. Independent management of medications is the key to health literacy.

Customer Service and Retainment

ScripTalk[®] Station affords your patients with simple and easy access to their prescription information and instructions. It also provides the opportunity for the pharmacy to offer personalized service and extend the pharmacy counter and benefits into the homes of the patients who need it most. You can expect increased sales, greater patient retention, new customer base and loyalty. ScripTalk[®] Station allows you to maximize customer benefits with minimal pharmacy effort.

Compliance

Federal regulations regarding services to individuals with disabilities have undergone a number of recent updates and changes. Pharmacies are under more pressure than ever to provide public accommodations in their services. Not only is ScripTalk[®] Station a low-cost, low-impact solution, it is the only product on the market that can provide the information required by the FDCA for prescription labels and confidential communication required by HIPAA to protect patient privacy. It is also a critical aid/service that will ensure effective communications to your visually impaired patients.



**En-Vision
AMERICA™**

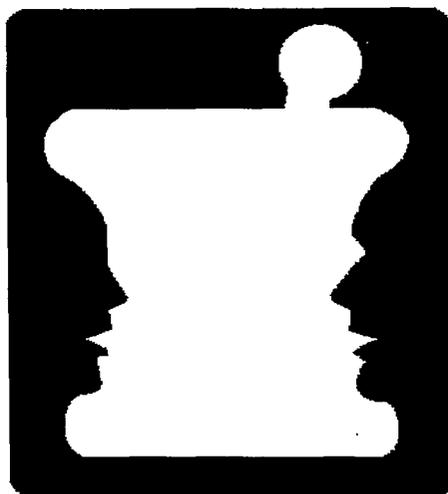
For more information or to begin ScripTalk service in your pharmacy, please contact us at:

1-800-890-1180 or www.envisionamerica.com

Agenda Item 5

Attachment I

State of California
Board of Pharmacy
Report to the Legislature



Prescription Drugs: Labeling Requirements
January 2010

Arnold Schwarzenegger, Governor
Kenneth H. Schell, PharmD, President, Board of Pharmacy
Virginia Herold, Executive Officer, Board of Pharmacy

Summary

The California Patient Medication Safety Act (Chapter 470, Statutes 2007) requires the Board of Pharmacy to promulgate regulations on or before January 1, 2011, that require a standardized, patient-centered prescription drug container label for all prescription drugs dispensed to patients in California. This Act further requires the board to report to the Legislature by January 1, 2010, on its progress in implementing these regulations.

This report summarizes the Board of Pharmacy's efforts to establish a standardized, patient-centered prescription drug label.

After approximately 18 months of public discussion regarding a standardized, patient-centered prescription label and gathering information at public forums, hearings, board and committee meetings, and conducting patient surveys, the board issued on November 20, 2009 proposed regulatory text to add section 1707.5 to Title 16 of the California Code of Regulations. This proposed section contains California's requirements for patient-centered prescription labels. The board will take action on this proposed regulation at its next scheduled meeting scheduled in January of 2010.

Background

In 2005, Senator Jackie Speier authored Senate Concurrent Resolution 49 (SCR 49), Chapter 123 Statutes of 2005, to create a multidisciplinary panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. As required, that panel prepared and submitted to specific legislative committees a final report (referenced as the SCR 49 Report) containing its conclusions and recommendations. The report reflected improvements, additions or changes which would reduce errors associated with the delivery of prescription and over-the-counter medications to consumers.

One bill was pursued based on the recommendations of the SCR 49 panel's report. Senator Ellen Corbett authored SB 472, resulting in enactment of the California Patient Medication Safety Act (Chapter 470, Statutes of 2007), Business and Professions Code section 4076.5. Therein, the Legislature stated the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling—which could increase consumer protection and improve the health, safety and well-being of consumers. Additionally, the Legislature affirmed the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems to identify and encourage the adoption of structural safeguards related to prescription drug container labels. To further these objectives, the Legislature mandated that the Board of Pharmacy adopt regulations to implement a standardized, “patient-centered” prescription drug container label in California.

SB 472 Medication Label Subcommittee

Legislation required that the board initiate public hearings to collect information from the public to facilitate the development of a regulatory proposal. The Board of Pharmacy president appointed a SB 472 Medication Label Subcommittee in January of 2008 to conduct public forums and to work with organizations and individuals to develop recommendations to implement the provisions of SB 472 to establish a patient-centered prescription drug label.

The SB 472 Medication Label Subcommittee held public forums on the following dates, apart from regularly-scheduled board meetings.

April 12, 2008

January 27, 2009

November 20, 2008

March 12, 2009

Agendas for these meetings are provided in Attachment 1.

At these public forums and at other board and board sub-committee meetings, as directed by the SB 472 Label Subcommittee, the board considered testimony and information provided from the public, the pharmaceutical industry, pharmacy professionals and literacy subject matter experts on medical literacy research, improved directions for use, improved font types and sizes, the placement of information that is patient-centered, the needs of patients with limited English proficiency, the needs of senior citizens, and technology requirements necessary to implement the standards developed. Board members were also provided with research

articles on designing patient-centered labels. The information and data received helped frame draft regulatory text to implement the provisions of SB 472.

Public and Community Outreach / Survey

Responding to minimal public input regarding the public's concerns about the current medication prescription labels that are used, the board developed a survey (Attachment 2) that could be provided and/or conducted one-on-one with participants at public outreach events, such as health fairs, where the board provides consumer information. This survey was provided in English and in Spanish. The survey was posted on the board's public Web site from May 2008 through November 2009. Survey questions were open-ended, allowing participants to provide as little or as much information as desired, but the questions did not direct participants to pre-defined responses. Survey results were provided to the board at SB 472 Subcommittee meetings, and also at regularly-scheduled board meetings.

Attachment 3 lists those organizations and individuals to which the survey was distributed to solicit input. Attachment 3 also contains a list of public outreach events at which board staff interviewed consumers and provided printed surveys to solicit input.

At public outreach events and at board and committee meetings, the public was provided with fact sheets entitled "Do you understand the directions on your Rx medicine label?" (Attachment 4) and demonstrated samples of faux prescription labels serving as visual aids.

The board also worked with the Pharmacy Foundation of California to develop a multi-choice survey of four questions that were available via a radio-sponsored survey. The goal was to identify key attitudes, knowledge and behaviors of California consumers related to prescription drug labels. The survey was conducted via Entercom Broadcasting and was made available in January 2009 on radio station Web sites that stream their audio. Results of this survey were provided to the SB 472 Medication Label Subcommittee at its meeting held March 12, 2009.

Proposed Regulatory Text

To implement the provisions of Business and Professions Code section 4076.5 (the California Medical Safety Practice Act) the board proposed text to add section 1707.5 to Title 16 of the California Code of Regulations (Attachment 5).

By providing a uniform, standardized format for prescription drug container labels and requiring pharmacies to provide oral language translations to patients with limited English proficiency, the Board believes that this proposed regulation will aid in the reduction of medication errors associated with the delivery of prescription drugs dispensed to patients in California.

Specifically, the regulatory language proposed on November 20, 2009, specifies the following:

- What components of a prescription label are considered “patient-centered”
- The font type, font size, wording and placement of specified components of a prescription label
- The Board will publish on its Web site by October 2011 translations of specified directions for use into at least five (5) languages other than English
- The Board will publish on its Web site by October 2010 examples of prescription labels that conform to the requirements of the regulation
- A pharmacy, upon request of a patient, shall provide oral interpretive services of the “patient-centered” elements of the prescription label, and
- The Board will re-evaluate the requirements of the regulation by December 2013 to ensure optimal conformance with the California Patient Medication Safety Act (Business and Professions Code section 4076.5)

Contained within the provisions of the proposed regulation, the board will publish on its Web site by October 2011 translations of the “directions for use” as specified in the proposed regulations, into at least five (5) languages other than English. The board will work with research health care advocates to develop these translations.

To assist those with limited English proficiency, and upon request by a patient, the proposed regulations will require a pharmacy to provide an oral language translation of the “patient-

centered” components of a prescription label, as specified in the proposed regulatory language.

At its board meeting held October 20, 2009, representatives from chain and retail pharmacy representatives stated that their existing oral language translation services provided to insured patients would be extended to cover all non-English speaking patients, if requested, with no further economic impact on their industry. The board commends the pharmacy industry for recognizing this significant component of delivering prescription drugs, and for meeting the needs of these patients.

Finally, the board included in its proposed regulations a requirement that it will re-evaluate the requirements of the regulations by December 2013 to ensure the effectiveness of the regulation in light of the factors contained in the California Patient Safety Medication Act (e.g., new developments in technology).

Regulation Schedule

The board issued proposed regulatory text on November 20, 2009. A 45-day comment period will close on January 4, 2010.

In addition, the board has scheduled a regulation hearing for January 20, 2010, in Sacramento. At that time, the board will accept written and verbal testimony and comments concerning the draft proposal. This hearing will be conducted prior to its regularly scheduled public Board Meeting that

same day and the board, at that time, may take action to adopt, amend, or to not move forward with the proposed regulation.

The board also scheduled a public Board Meeting for February 17, 2010, in anticipation of the need for a 15-day comment period of modified text following the regulation hearing and Board Meeting.

The board believes this regulation schedule will allow industry approximately ten months to prepare for the implementation of new regulatory requirements. The board also believes its current Board Meeting schedule will allow it to address the needs of industry and the public, and provide for the required reviews prior to implementing a regulation by the January 2011 mandate contained in SB 472.



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

**Notice of Public Meeting
April 12, 2008**

Wally Pond Irvington Community Center
41885 Blacow Road
Fremont, CA

10 a.m. – 2 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Leech at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the Board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order

10 a.m.

1. Invitation to Participate in the Redesign of Prescription Container Labels
Committee Chair Ken Schell, PharmD
2. Opening Remarks
The Honorable Ellen Corbett, California Senator, District 10
3. Presentation of SCR 49 findings, and the need for patients to understand their drug therapy as a source of reducing medication errors.
Michael Negrete, PharmD
4. Requests for Public Comment on the Following: What works on prescription container labels? What does not? How can prescription container labels be improved to make them patient-centered?
5. Timeline for Project
6. Future Meeting Dates

Adjournment

2 p.m.



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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF PUBLIC BOARD MEETING OF THE CALIFORNIA STATE BOARD OF PHARMACY

FORUM ON DESIGNING PATIENT-CENTERED PRESCRIPTION LABELS

November 20, 2008
1:30 p.m. - 4:30 p.m.

The Westin Los Angeles Airport Hotel
5400 West Century Boulevard
Lindberg A and B Meeting Rooms
Los Angeles, CA 90045

Contact: Virginia Herold
(916) 574-7911

This forum is hosted by the California State Board of Pharmacy as part of the board's efforts to develop standards for prescription labels by 2011 that will be patient-centered, and to implement the California Medication Safety Act (SB 472, Corbett, Chapter 470, Statutes of 2007). The goal is to foster better patient understanding of the information on a label as a means to reduce medication errors, and improved patient well-being. The public is invited to attend.

This meeting is open to the public (no pre-registration is required) and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Gallagher at (916) 574-7912, at least five working days prior to the meeting. Opportunities are provided to the public to address the board on each open agenda item. Action may be taken on any item on the agenda by the Board of Pharmacy. All times are approximate and subject to change.

-
1. **Welcoming Remarks** 1:30 p.m.
Kenneth Schell, PharmD, President, California State Board of Pharmacy
 2. **Improving Prescription Container Labels – What is the Status of the Research**
Michael S. Wolf, PhD, MPH, Feinberg School of Medicine, Northwestern University
Stacy Cooper Bailey, MPH, Feinberg School of Medicine, Northwestern University
 3. **Patient Health Literacy in the U.S. and its Impact on Health**
Michael Villaire, MSLM, Director Programs and Operations, Institute for Healthcare Advancement
 4. **Perspective of the Latino Coalition for a Healthy California to Improve Prescription Container Labeling**
Vanessa Cajina, Director, Regional Networks Coordinator, Latino Coalition for a Healthy California
 5. **Perspective of California's Seniors to Improve Prescription Container Labeling**
 6. **Summary of Patient Surveys Collected During 2008 by the California State Board of Pharmacy**
Virginia Herold, Executive Officer, California State Board of Pharmacy
 7. **Next Steps**
 8. **Public Comments for Items Not on the Agenda**
 9. **Adjournment** 4:30 p.m.



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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting
January 27, 2009

Sheraton Hotel - Mission Valley
1433 Camino Del Rio South
San Diego, CA, 92108
(619) 260-0111

1 – 5 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tess Fraga at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order

1 p.m.

1. Welcoming Remarks
Subcommittee Chair Ken Schell, PharmD
2. Review of Consumer Surveys Conducted by the Board of Pharmacy
3. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy
4. Review of California's Requirements for Prescription Container Labels (California Business and Professions Code Section 4076)
5. Timelines for Project Deliverables
6. Public Comment
7. Future Meeting Dates

Adjournment

5 p.m.



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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting

March 12, 2009

Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834
(916) 574-7900
6 - 9 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tess Fraga at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order

6 p.m.

1. Welcoming Remarks
2. Review of SB 472 and the Charge to the Board in Developing Patient-Centered Labels
3. Overview of SB 853 (Escutia, Chapter 713, Statutes of 2003) Health Care Language Assistance
4. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472
5. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy for SB 472
6. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)
7. Legislative Proposal to Add "Purpose" to Prescription Container Labels
8. Public Comment for Items Not on the Agenda
(Note: the committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))

Adjournment

9 p.m.



CONSUMERS – we want to hear from you!

Do you have suggestions to improve prescription container labels? The California State Board of Pharmacy welcomes your feedback to make labels more patient-friendly with directions that are easier to read and understand.

What information on the label is most important to you?

Do you understand the directions?

What would you change on the label?

What would make the label easier to read?

Other suggestions:

City: _____ Date: _____



Examples of warning labels



Printed information in different colors



Examples of different container shapes and sizes requiring different types of labels



Directions for use or how to take the drug

THANK YOU for your feedback.
Please return your completed form to:

Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834



CONSUMIDORES – ¡Queremos oír de usted!

¿Tiene usted sugerencias para mejorar las etiquetas del envase de recetas? La Junta de Farmacia del Estado de California da la bienvenida a su reacción para hacer etiquetas más-paciente amistosas con las indicaciones que son más fáciles de leer y comprender. Gracias por su reacción.

¿Qué información en la etiqueta de la receta es más importante para usted?

¿Comprende usted las instrucciones en la etiqueta de la receta?

¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ Fecha: _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834



CONSUMIDORES – ¡Queremos oír de usted!

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¿Qué cambiaría usted en la etiqueta de la receta?

¿Qué haría la etiqueta de la receta más fácil de leer?

Ciudad: _____ Fecha: _____

Vuelva por favor su forma completada a: Virginia Herold, California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834

California State Board of Pharmacy Prescription Label Survey

OBJECTIVE: To elicit feedback from consumers in California regarding development of patient-centered prescription drug labels pursuant to Senate Bill 472 (Chapter 470, Statutes of 2007)

METHODOLOGY: A survey was developed by the California State Board of Pharmacy (Board) in May 2008. The questions were open-ended, allowing participants to provide as little or as much information as desired. Board staff used the survey to interview consumers at public outreach events including health/community fairs in Sacramento, Elk Grove, Los Angeles, Riverside, San Diego, Merced, and San Francisco. Printed surveys and self-addressed return envelopes were provided to attendees who chose to return responses by mail. The survey was provided in English and Spanish. The board also provided fact sheets entitled, "Do you understand the directions on your Rx medicine label?" and samples of faux prescription labels serving as visual aids. The survey was posted on the Board's public website and to interested parties and organizations including the Gray Panthers and the Latino Coalition for a Healthy California. Board members also interviewed consumers, and returned the responses by mail.

RESULTS: A total of 622 surveys were received as of March 3, 2009. The majority of respondents provided one or more answers to the first two questions, but did not always provide answers to subsequent questions. Respondents gave similar answers to multiple questions within a survey (i.e., request for large print). Attached graphs reflect detailed responses; most frequent responses summarized below.

When asked what information on the prescription label was most important, the top responses were:

Directions for use (224 of 1,207 responses = 18.6%)

Name of drug; if generic, state generic name AND brand name (222 of 1,207 responses = 18.4%)

Dosage prescribed (213 of 1,207 responses = 17.6%)

Side effects/warnings/interactions/contraindications (122 of 1,207 responses = 10.1%)

Purpose of drug – state what condition medication is prescribed to treat (84 of 1,207 responses = 7%)

When asked what to change on the prescription label, the top responses were:

Print should be larger or darker (170 of 568 responses = 30%)

Nothing needs to be changed on the label (139 of 568 responses = 24.5%)

Include purpose of drug – state what condition medication is intended to treat (69 of 568 responses = 12.1%)

When asked what would make prescription labels easier to read, the top response was:

Larger or bolder print (314 of 522 responses = 60%)

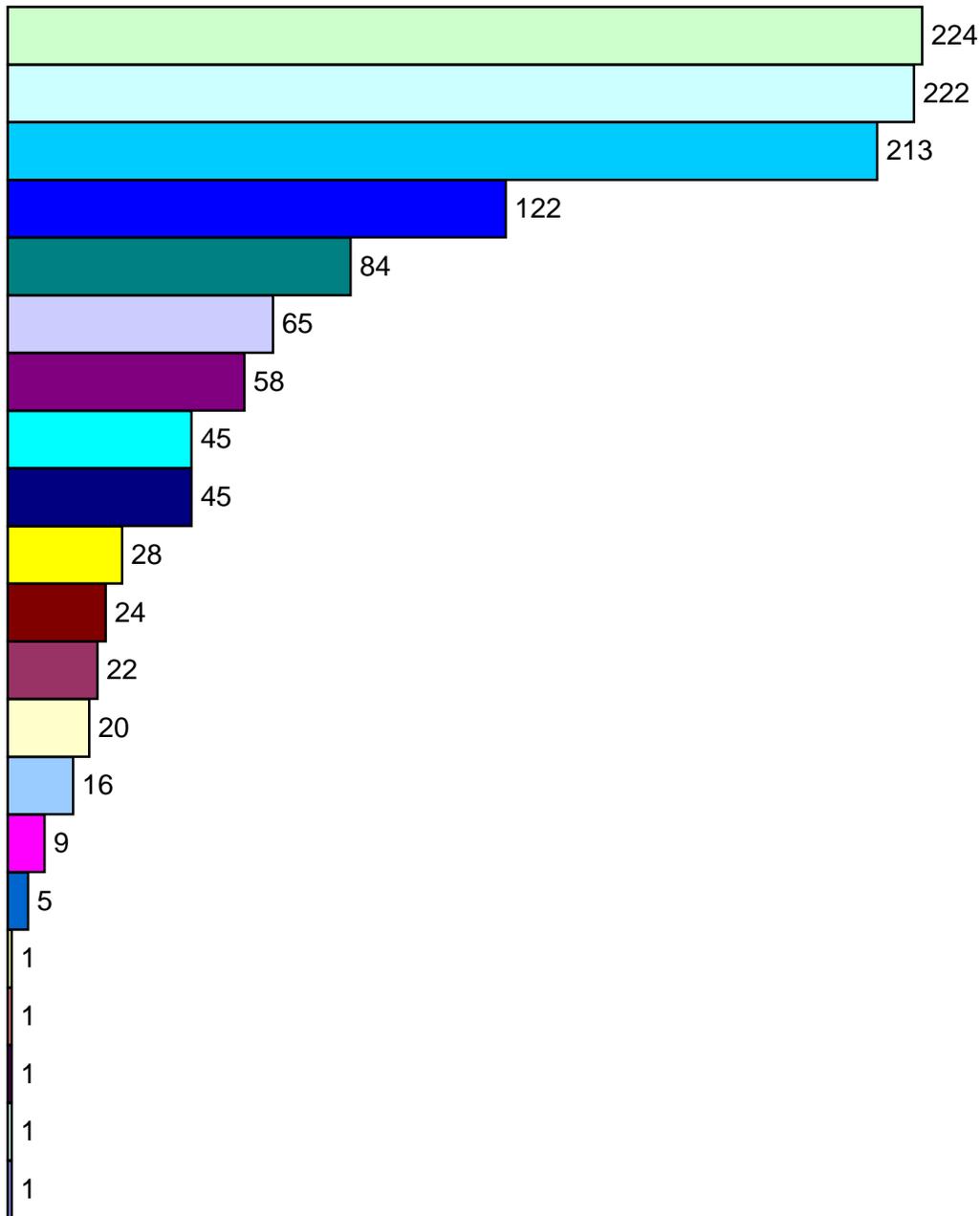
When asked for other suggestions, the top responses were:

Easy-open lids/packages should be used; no child-proof caps for seniors (20 of 134 responses = 14.9%)

Include purpose of drug - state what condition medication is intended to treat (17 of 134 responses = 12.7%)

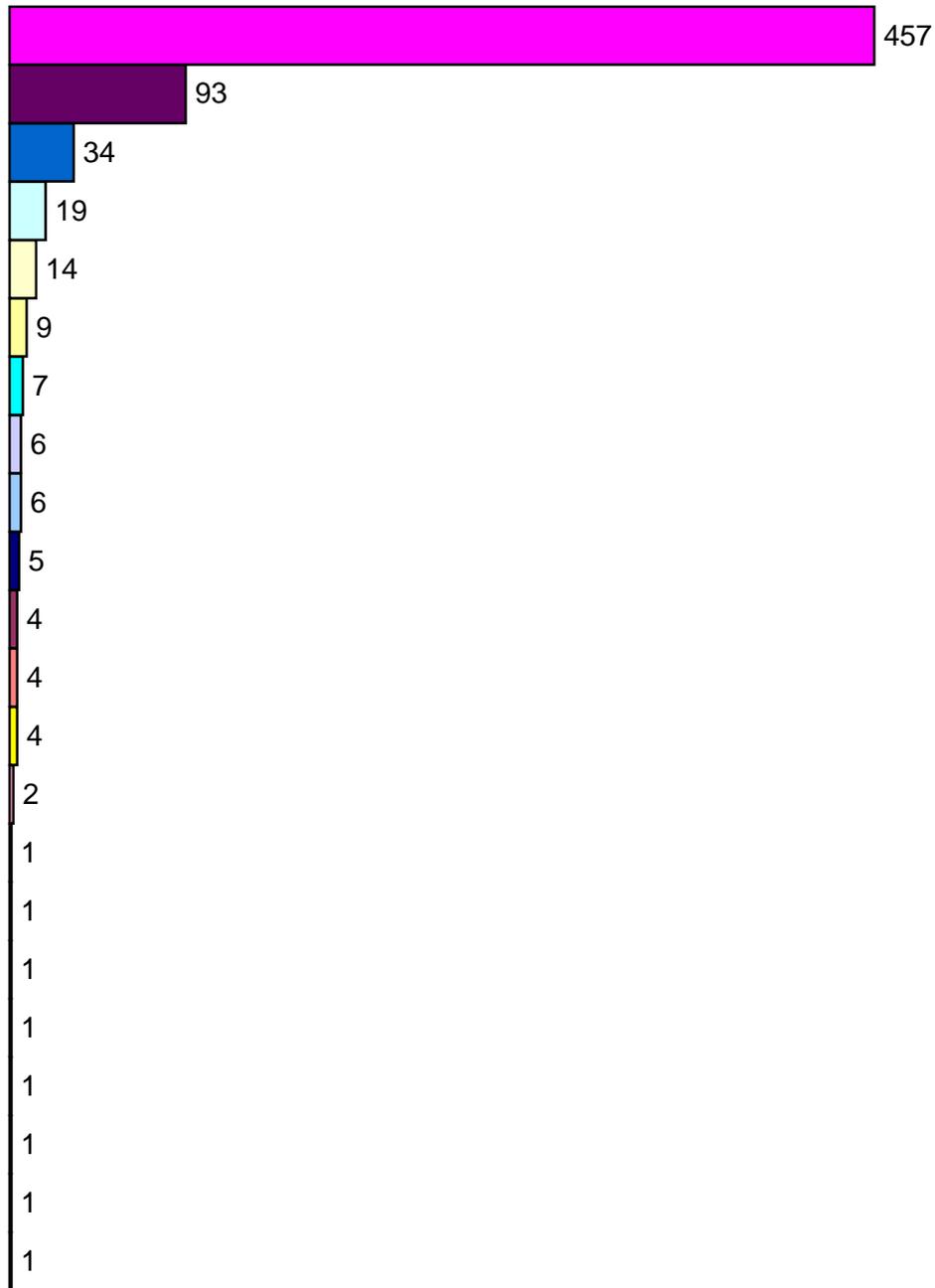
CONCLUSIONS: Most consumers participating in this survey requested larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. They also noted that color printing and highlighting on labels brings attention to important information. Some participants suggested that the labels themselves be color-coded to help differentiate between multiple medications and family members. Many consumers want to know 'what the drug is for' and suggested that 'purpose of drug' be printed directly on prescription labels.

QUESTION #1: What information on the label is most important to you?
622 surveys returned (1,207 responses to Question #1) as of March 3, 2009



- Directions for use
- Name of drug; if generic, state generic name AND brand name
- Dosage prescribed
- Side effects/warnings/interactions/contraindications
- Purpose of drug; what condition medicine is intended to treat
- Specific times during day to take medicine (and with, w/o food)
- Refill renewal/reorder information/expiration; date filled
- Patient name (some also suggested patient's date-of-birth)
- Expiration date of drug
- Large or bold print
- Phone numbers (NOT printed in close proximity to each other)
- Prescribing doctor's name
- Description of pill (shape/color)
- Prescription number
- All information on label is important
- Name of drug store/pharmacy/pharmacist
- With a large family, keep all prescriptions in the same place
- Diabetes information
- Highlighting information including directions for use
- Basic measurements (e.g., teaspoons, not milligrams)
- Don't hide important information under another label

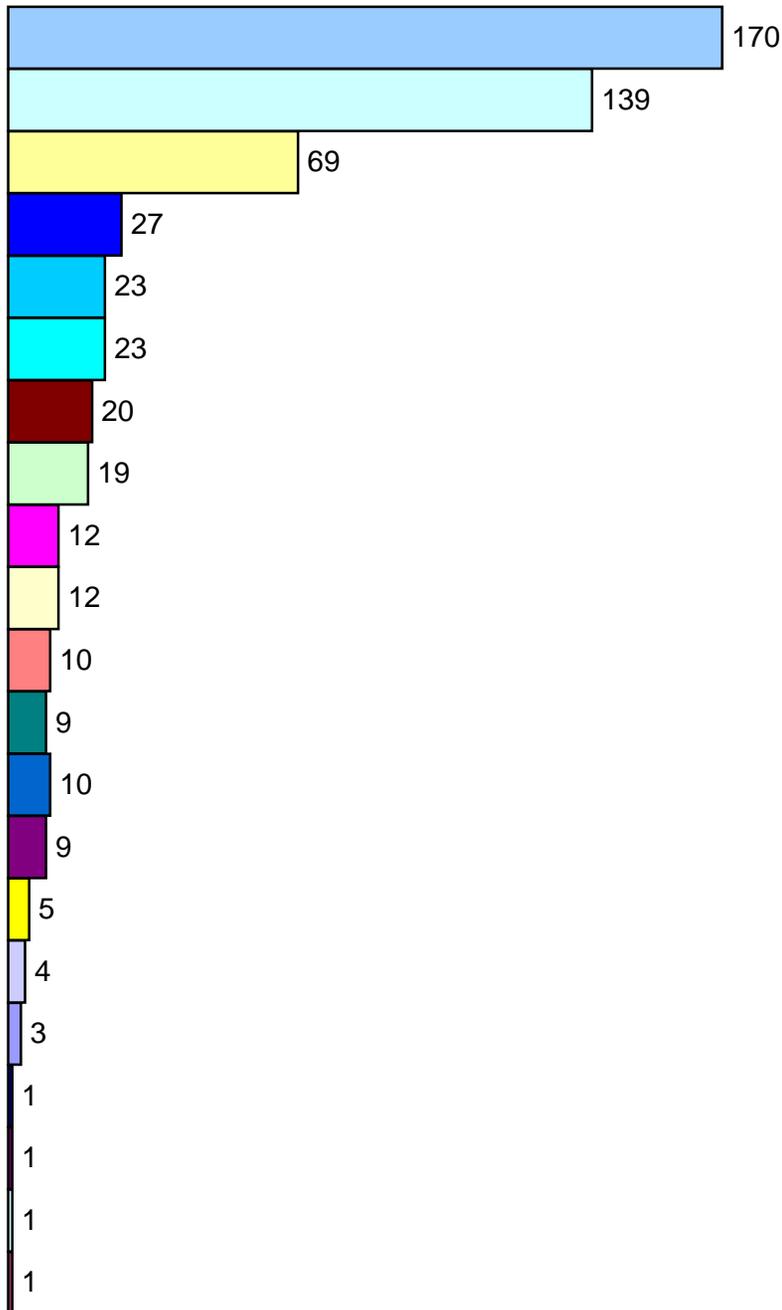
QUESTION #2: Do you understand the directions on the prescription label?
622 surveys returned (672 responses to Question #2) as of March 3, 2009



- Yes
- Usually (though print may be too small, directions/warnings unclear)
- Sometimes
- No (i.e., trouble understanding or not enough space for directions)
- Directions should state what time(s) to take medicine and how much
- Would be helpful to know whether to take with or without food
- I understand because I'm RN, Dr, health worker, have biology degree
- Not when there is a language barrier
- What does 2x (or 3x, or 4x) a day mean?
- Directions need clarity (2 pills = 1 pill twice/day or 2 pills twice/day?)
- Instructions should be in English and Spanish
- Instructions should be in English and Spanish
- Abbreviations should be eliminated
- I do not understand directions that only say "Take as directed"
- No long paragraphs on prescription label
- Label from Kaiser understandable, label from Rite Aid not as clear
- Bullets and spacing on label would be helpful
- Handout should be more readable
- Accompanying paper shouldn't be complicated - use bullets/spacing
- When I don't understand the directions, I ask the pharmacist
- Pharmacist's directions are vague during consultation
- The directions often conflict with the doctor's orders

QUESTION #3: What would you change on the prescription label?

622 surveys returned (568 responses to Question #3) as of March 3, 2009



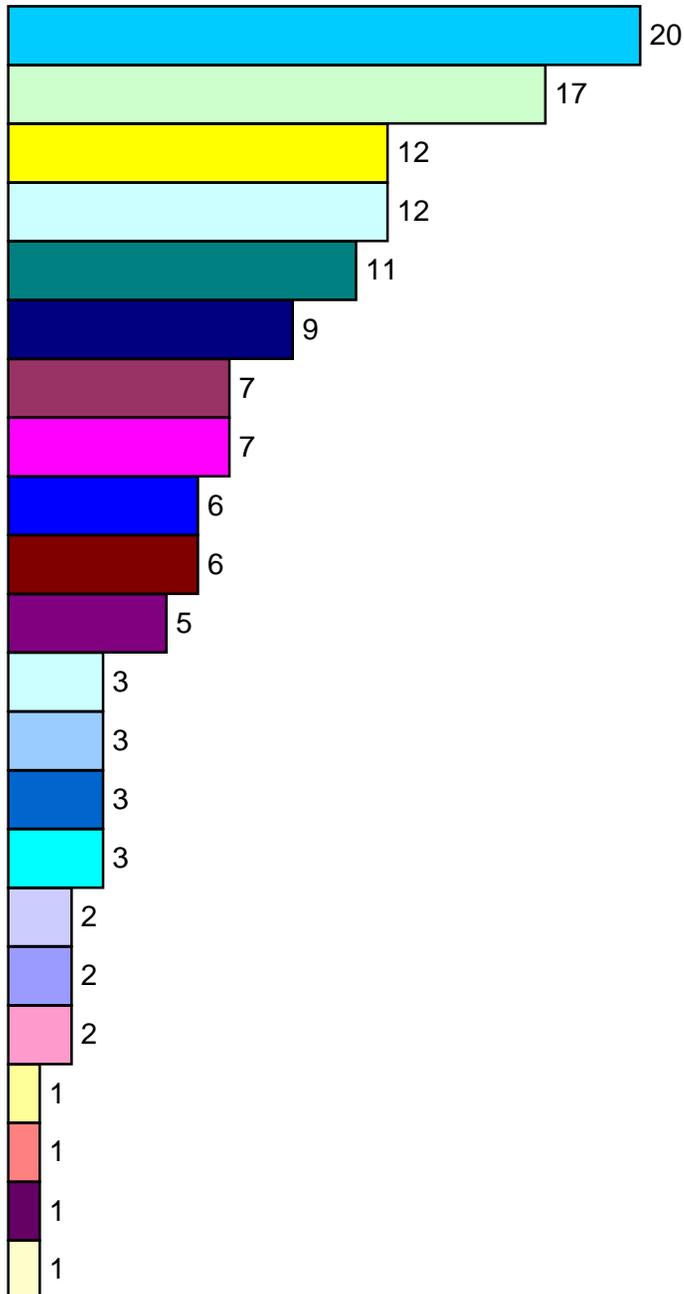
- Print should be larger or darker (legibility)
- Nothing needs to be changed (some referred to Kaiser, Target, Raley's, CVS)
- Include purpose of drug - state what condition medication is intended to treat
- Information printed should be understandable for all ages; layman's terms
- Use bold or highlighted print or capital letters; red/blue ink for warning labels
- Use different colors for different medicines, strengths/doses, family members
- Directions should include specific times (or morning/night) to take medicine
- Make warning labels easier to read or print directly on label instead of auxilliary
- Name of drug; if generic, state generic name AND brand name
- Refill info (i.e., date to reorder or if no refills remain, state "0 refills remain")
- Include direct phone numbers for easier communication with doctor/pharmacy
- Print in patient's primary language; bilingual wording
- Standardize location of info; uniform label; show information in same order
- Delete unneeded info (i.e., don't say take tab "by mouth" or show address)
- Should be less advertising on label; remove unnecessary information
- Use ink that does not disappear, fade, rub off, or smudge
- Make "fold-out" label or "lift-open flap" stating side effects or purpose of drug
- If more than 1 label, show as "label #1" and "label #2"
- Use only one color on label
- More than one name for medicine is confusing at times
- Label should not refer patient to internet web site

QUESTION #4: What would make the prescription label easier to read?
622 surveys returned (522 responses to Question #4) as of March 3, 2009



QUESTION #5: Other suggestions?

622 surveys returned (134 responses to Question #5) as of March 3, 2009



- Easy-open lids/packages should be used; no child-proof caps for seniors
- Include purpose of drug - state what condition medication is intended to treat
- Bigger or darker font (i.e., drug expiration date, directions for use, warnings)
- Use different color for printing some info (i.e., directions for use, pharmacy phone #)
- Make directions simple/clear/understandable; print in patient's primary language
- Make bottles rectangular or square w/flat surface and directions printed on long side
- Put picture of pill on label or photo of pill or description of pill
- Side effects/interactions should be stated (i.e., dry mouth may cause dental caries)
- Different colored bottles or caps would help identify medications
- Standardize location of info so all prescriptions show information in same order
- Make label easy to remove (to recycle bottle or for privacy/security when discarding)
- Note on label when the manufacturer of the medicine changes
- Show where to return outdated meds or option to dispose via pharmacy
- Don't cover prescription number with warning labels; use symbols as warnings
- Bottles should be in travel/airplane size; large bottles are clumsy and take up space
- Use top of lid for info; containers opening at bottom leave room for larger label
- Note change in size, color, shape of pills, so won't be perceived as medication error
- State what to do if you miss a dose
- Allow NP's name to appear on Rx bottle when submitting electronic prescriptions
- Labels should be waterproof
- Don't allow label to completely cover bottle; leave space to see medication remains
- Include a plan w/multiple meds (i.e., interactions, don't take with Calcium, etc.)

**COMMUNITY ORGANIZATIONS AND OTHER ENTITIES
PROVIDED WITH BOP PRESCRIPTION LABEL SURVEYS 2008/09**

The organizations and individual entities listed below were provided with English and Spanish versions of the California State Board of Pharmacy Prescription Label Survey during 2008/09.

- | | |
|---|--|
| <p>1. Casey Young AARP State Legislative Director 1415 L Street, #960 Sacramento, CA 95814 (916) 556-3018 cyoung@aarp.org</p> | <p>7. Sandra Fitzpatrick, Director California Commission on Aging 1300 National Drive, Suite #173 Sacramento, CA 95834 (916) 419-7591 sfitzpatrick@ccoa.ca.gov</p> |
| <p>2. Sam Totah Kaiser Permanente 10990 San Diego Mission Road San Diego, CA 92108 sammy.r.totah@kp.org</p> | <p>8. Steve Blackledge CalPIRG 1107 9th Street, Suite #601 Sacramento, CA 95814 (916) 448-4516 Sblackledge@calpirg.org</p> |
| <p>3. Vanessa Cajina Latino Coalition for a Healthy California 1225 8th Street, Suite 500 Sacramento, CA 95814 (916) 448-3234 vcajina@lchc.org</p> | <p>9. Betty Williams, Executive Director Network for Elders 1555 Burke Avenue, Suite A San Francisco, CA 94123 (415) 647-5353 bwilliams@networkforelders.org</p> |
| <p>4. Nancy Kawahara, PharmD Associate Professor of Pharmaceutical Sciences 11262 Campus St, West Hall, Room 1334 Loma Linda, CA 92350 nkawahara@llu.edu</p> | <p>10. Julia Ling, Executive Director Chinese Newcomers Foundation 777 Stockton Street, #104 San Francisco, CA 94108 (415) 421-2111 julialing@msn.com cnscc@chinesenewcomers.org</p> |
| <p>5. Barry Goggin, President Better Business Bureau of Sacramento Valley 400 S Street Sacramento, CA 95814 (916) 443-6843 info@necal.bbb.org</p> | <p>11. Gary Passmoore, Legislative Coordinator Congress of California Seniors 1228 N Street, #29 Sacramento, CA 95814 (916) 442-4474 GaryP@seniors.org</p> |
| <p>6. Lu Molberg Ca. Assn. of Area Agencies on Aging 980 9th Street, Suite 2200 Sacramento, CA 95814 (916) 443-2800 C4a@pacbell.net</p> | <p>12. Joe Ridout, Consumer Advice Counselor Consumer Action 221 Main Street, Suite #480 San Francisco, CA 94105 (415) 777-9648</p> |

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Kathy Li, Director
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consumer.mediation@sfgov.org
17. Brad Chibos
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San Jose, CA 95125
(408) 998-1694 Chibos@aol.com
18. Marina Community Center
Senior Services Office
15301 Wicks Blvd.
San Leandro, CA 94579
19. Lavender Seniors of the East Bay
1395 Bancroft Avenue
San Leandro, CA 94577
20. East Bay Services for the Developmentally
Disabled
797 Montague Ave.
San Leandro, CA 94577
21. Evergreen Senior Program/Wisdom Path
985 Suerro Street
Hayward, CA 94541
22. Hayward Area Senior Center
22325 N. 3rd Street
Hayward, CA 94546-6969
23. Kenneth Aitken Senior & Community
Center
17800 Redwood Road
Castro Valley, CA 94546
24. Ralph & Mary Ruggieri Senior Center
33997 Alvarado-Niles Road
Union City, CA 94587
25. Newark Senior Center
7401 Enterprise Drive
Newark, CA 94560
26. Fremont Multi-Service Senior Center
40086 Paseo Padre Parkway
Fremont, CA 94538
27. Barbara Lee Senior Center
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Los Angeles, CA 90015
40. Michael Villaire, MSLM
Director, Programs & Operations
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La Habra, CA 90631
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Gardena, CA 90249
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47. Helen Park
helen.park@va.gov

**PUBLIC OUTREACH EVENTS WHERE BOP STAFF INTERVIEWED ATTENDEES AND
COMPLETED BOP PRESCRIPTION LABEL SURVEYS**

1. Meet The Pharmacist – San Diego – May 2008
2. Senior Day in The Park – Elk Grove – May 2008
3. Better Business Bureau Community Alliance Day – Merced – June 2008
4. Eddie Smith Senior Center – Riverside – June 2008
5. Safetyville Family Safety Expo – Sacramento – June 2008
6. Lotus Festival – Los Angeles – July 2008
7. California State Fair – Sacramento – August 2008
8. Celebrando Nuestra Salud – Sacramento – October 2008
9. Evans Community Adult School Consumer Fair – Los Angeles – March 2009

CALIFORNIA STATE
BOARD OF PHARMACY



(916) 574-7900
WWW.PHARMACY.CA.GOV
1625 N. MARKET BLVD.
SUITE N-219
SACRAMENTO, CA 95834



Do you understand the directions on your Rx medicine label?

Approximately 46% of American adults do not.

A prescription label says to "Take two tablets by mouth twice daily." Sounds simple, doesn't it?

But patients have understood this to mean:

- Take it every 8 hours
- Take it every day
- Take one every 12 hours

Better directions might be "Take 2 tablets by mouth at 8 in the morning, and take 2 tablets at 9 at night."

FACT: Six out of 10 people have taken their medicines incorrectly, due to:

- confusing directions on the container label,
- poor health literacy (the ability to read, understand, and act on healthcare information), and
- inability to read and/or understand directions written in English of those whose first language is not English.

FACT: Medicine errors are among the most common medical errors, harming at least 1.5 million people every year. More than one third of these take place outside a hospital in a home setting, costing close to \$1 billion annually.

FACT: Up to one-half of all medicines are taken incorrectly or mixed with other medicines that can cause dangerous reactions that can lead to injury and death.

Medicine-related errors must be reduced. One way to begin is by providing patients with easy to read and understand prescription container labeling. This can be a giant step toward increasing consumer protection and improving the health, safety, and well-being of consumers.

California recognizes the importance of improving medicine container labels. In 2007, the Legislature and Governor Schwarzenegger enacted Senate Bill 472, mandating the Board of Pharmacy to develop requirements for standardized, patient-centered, prescription drug labels on all prescription medicine dispensed to patients in California.

In 2008, the Board will hold statewide public meetings to consult with patients and health providers to improve prescription container labels. The meetings will focus on improving directions for the drug's use, using better type fonts and sizes, and placement of information that is patient-centered. The needs of senior citizens and patients with limited English reading skills also will be identified.

sample prescription labels

OUS/pharmacy #0000 Ph: 555-555-5555 PC

000 WEST AVE
DAVIS, CA 95618

SODERGREN, ANNE
1625 N MARKET BLVD
Sacramento, CA 95834

PRESCRIBER:
Perez, Victor

Rx: 000000

USE INTRAMUSCULARLY
LATERAL THIGH AS NEEDED
FOR SEVERE ALLERGIC
REACTION

EPIPEN 0.15 MG/2-PAK AUTO-IDEY
PHARM FARM

Refillable 3 times before 01-03-2008
HAGEN, VERONICA Techs LK PCSUE DURST
Date filled: 01-03-2007 Orig Date: 01/03/2007 Discard After:

KENNETH'S PHARMACY

Refill Phone:
(555) 555-5555
www.AP.com

DESSERT MEDICAL/030
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834
(555) 555-5555

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.

Rx# 000000 TAMRAZ, HOPE MD 11/12/07 PXA

PEREZ, VICTOR I

TAKE 1 TABLE SPOON THREE TIMES A DAY AS NEEDED FOR
COUGH

PROMETHAZINE/CODEINE SYRUP
QTY: 480ML Mfr: PHARM FARM

Discard: (FOR: PHENERGAN/CODEINE)

CLEAR, PURPLE-RED, PEACH-MINT, SYRUP.

Please call 48 hrs in advance for refills.

Linda's Drugs Linda's HEALTHCARE TAKE MEDICATION WITH FOOD

Store # 1025 N MARKET
SACRAMENTO, CA 95834
0000 24 HOUR PHONE (555) 555-5555

PEREZ, VICTOR MD
Rx: 000000 01/07/2008 HAH

Durst, Sue

TAKE 1 CAPSULE TWICE A DAY

Generic for ACTIGALL
URSODIOL 300 MG CAPSULE
60 (PHARM FARM) JISSU BY

WHITE, OBLONG CAPSULE
Front: PHARM Back: 0000

NO REFILLS

Title 16. Board of Pharmacy Proposed Language

To Add Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1707.5 Patient Centered-Labels on Medication Containers

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.
- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, sans serif typeface, and listed in the following order:
- (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.
 - (C) Directions for use
 - (D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is desired by the patient.
- (2) For added emphasis, the label may also highlight in bold typeface or color, or use "white space" to set off the items listed in subdivision (a)(1).
- (3) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a)(1), and may appear in any style and size typeface.
- (4) When applicable, directions for use shall use one of the following phrases:
- (A) Take 1 tablet at bedtime
 - (B) Take 2 tablets at bedtime
 - (C) Take 3 tablets at bedtime
 - (D) Take 1 tablet in the morning
 - (E) Take 2 tablets in the morning
 - (F) Take 3 tablets in the morning
 - (G) Take 1 tablet in the morning, and Take 1 tablet at bedtime

- (H) Take 2 tablets in the morning, and Take 2 tablets at bedtime
 - (I) Take 3 tablets in the morning, and Take 3 tablets at bedtime
 - (J) Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening
 - (K) Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening
 - (L) Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening
 - (M) Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime
 - (N) Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime
 - (O) Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime
 - (P) Take 1 tablet as needed for pain. You should not take more than ___ tablets in one day
 - (Q) Take 2 tablets as needed for pain. You should not take more than ___ tablets in one day
- (b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
- (c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
- (d) For patients who have limited English proficiency, upon request by the patient, the pharmacy shall provide an oral language translation of the prescription container label's information specified in subdivision (a)(1) in the language of the patient.
- (e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

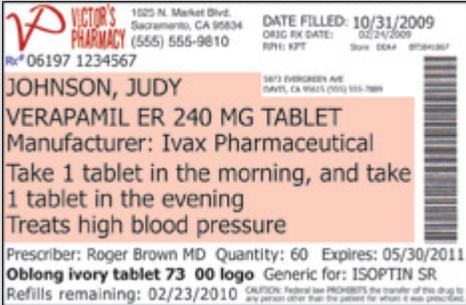
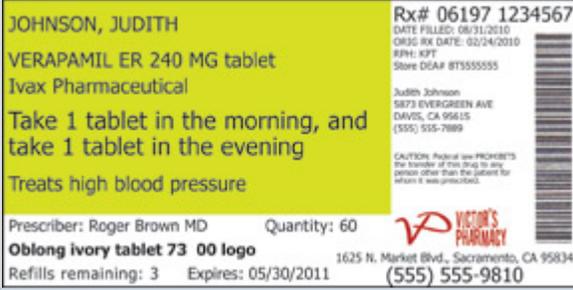
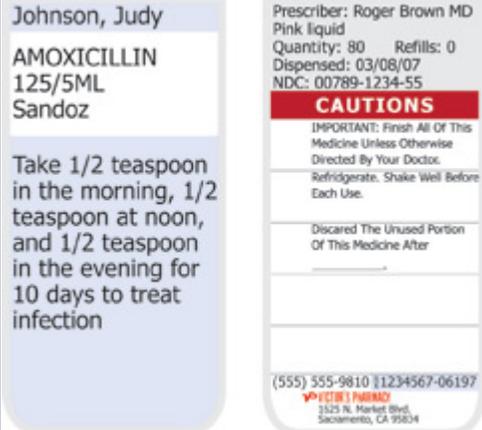
Authority cited: Sections 4005 and 4076.5, Business and Professions Code.

Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

Agenda Item 5

Attachment 2

Parameters

| | |
|--|--|
| <p>Label size: 8.29 x 5.43 cm</p> <p>Font family: Tahoma</p> <p>Font size: 12 pt</p> |  <p>1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810</p> <p>DATE FILLED: 10/31/2009 ORIG RX DATE: 02/24/2010 RPH: KPT Store DEAR BT5555557</p> <p>Rx# 06197 1234567</p> <p>JOHNSON, JUDY 5873 EVERGREEN AVE DAVIS, CA 95615 (555) 555-7889</p> <p>VERAPAMIL ER 240 MG TABLET Manufacturer: Ivax Pharmaceutical</p> <p>Take 1 tablet in the morning, and take 1 tablet in the evening Treats high blood pressure</p> <p>Prescriber: Roger Brown MD Quantity: 60 Expires: 05/30/2011 Oblong ivory tablet 73 00 logo Generic for: ISOPTIN SR Refills remaining: 02/23/2010</p> <p><small>CAUTION: Federal law PROHIBITS the transfer of this drug to any person other than the patient for whom it was prescribed.</small></p> |
| <p>Label size: 10.2 x 5.12 cm</p> <p>Font family: Franklin Gothic Book</p> <p>Font size: 10 pt</p> |  <p>1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810</p> <p>Prescriber: Roger Brown MD Oblong Ivory tablet 73 00 logo Refills remaining: 3 Quantity: Expires: 05/30/2011</p> <p>JOHNSON, JUDITH 1 AZOPT Ophth 1% Susp 10ml AL Mfg: Alcon Laboratories</p> <p>Instill 1 drop in each eye in the morning and 1 drop in each eye in the evening for glaucoma. *Do not use other eye drops for at least 10 minutes*</p> <p>Rx# 06197 1234567 DATE FILLED: 06/31/2010 ORIG RX DATE: 02/24/2010 RPH: KPT Store DEAR BT5555555</p> <p>Judith Johnson 5873 EVERGREEN AVE DAVIS, CA 95615 (555) 555-7889</p> <p><small>CAUTION: Federal law PROHIBITS the transfer of this drug to any person other than the patient for whom it was prescribed.</small></p> |
| <p>Label size: 10.2 x 5.12 cm</p> <p>Font family: Tahoma</p> <p>Font size: 10 and 12pt</p> |  <p>JOHNSON, JUDITH VERAPAMIL ER 240 MG tablet Ivax Pharmaceutical</p> <p>Take 1 tablet in the morning, and take 1 tablet in the evening Treats high blood pressure</p> <p>Prescriber: Roger Brown MD Quantity: 60 Oblong ivory tablet 73 00 logo Refills remaining: 3 Expires: 05/30/2011</p> <p>Rx# 06197 1234567 DATE FILLED: 06/31/2010 ORIG RX DATE: 02/24/2010 RPH: KPT Store DEAR BT5555555</p> <p>Judith Johnson 5873 EVERGREEN AVE DAVIS, CA 95615 (555) 555-7889</p> <p><small>CAUTION: Federal law PROHIBITS the transfer of this drug to any person other than the patient for whom it was prescribed.</small></p> |
| <p>Label size: 10.2 x 5.12 cm</p> <p>Font family: Franklin Gothic Book</p> <p>Font size: 12pt</p> |  <p>1625 N. Market Blvd. Sacramento, CA 95834 (555) 555-9810</p> <p>Prescriber: Roger Brown MD Oblong Ivory tablet 73 00 logo Refills remaining: 3 Quantity: Expires: 05/30/2011</p> <p>JOHNSON, JUDITH 1 AZOPT Ophth 1% Susp 10ml AL Manufacturer: Alcon Laboratories</p> <p>Instill 1 drop in each eye in the morning and 1 drop in each eye in the evening for glaucoma. *Do not use other eye drops for at least 10 minutes*</p> <p>Rx# 06197 1234567 DATE FILLED: 06/31/2010 ORIG RX DATE: 02/24/2010 RPH: KPT Store DEAR BT5555555</p> <p>Judy Johnson 5873 EVERGREEN AVE DAVIS, CA 95615 (555) 555-7889</p> <p><small>CAUTION: Federal law PROHIBITS the transfer of this drug to any person other than the patient for whom it was prescribed.</small></p> |
| <p>Label size: 3.99 x 7.83 cm each</p> <p>Font family: Tahoma</p> <p>Font size: 12pt</p> |  <p>Johnson, Judy AMOXICILLIN 125/5ML Sandoz</p> <p>Take 1/2 teaspoon in the morning, 1/2 teaspoon at noon, and 1/2 teaspoon in the evening for 10 days to treat infection</p> <p>Prescriber: Roger Brown MD Pink liquid Quantity: 80 Refills: 0 Dispensed: 03/08/07 NDC: 00789-1234-55</p> <p>CAUTIONS</p> <p>IMPORTANT: Finish All Of This Medicine Unless Otherwise Directed By Your Doctor. Refrigerate. Shake Well Before Each Use.</p> <p>Decared The Unused Portion Of This Medicine After</p> <p>(555) 555-9810 11234567-06197 VICTOR'S PHARMACY 1625 N. Market Blvd. Sacramento, CA 95834</p> |

| | |
|---|--|
| <p>Label size: 6.53 x 4.66 cm</p> <p>Font family: Arial</p> <p>Font size: 10 pt</p> | |
| <p>Label size: 15.91 x 3.21 cm</p> <p>Font family: Arial</p> <p>Font size: 10 pt</p> | |
| <p>Label size: 7.9 x 4.73 cm</p> <p>Font family: Tahoma</p> <p>Font size: 12 pt</p> | |
| <p>Label size: 12.1 x 5.12 cm</p> <p>Font family: Calibri</p> <p>Font size: 12 pt</p> | |
| <p>Label size: 13.97 x 5.72 cm</p> <p>Font family: Geneva</p> <p>Font size: 10 pt</p> | |
| <p>Label size: 12.08 x 5.4 cm</p> <p>Font family: Tahoma</p> <p>Font size: 12 pt</p> | |

Agenda Item 6

Attachment I

FORTY-FIRST ANNUAL REPORT
of the
RESEARCH ADVISORY PANEL
OF CALIFORNIA
2011



PREPARED FOR THE
LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA

455 Golden Gate Avenue - Suite 11000
San Francisco, California 94102-7004

www.ag.ca.gov/research

TABLE OF CONTENTS

| | Page |
|--|------|
| LIST OF 2011 PANEL MEMBERS | 2 |
| SUMMARY OF 2011 PANEL ACTIVITIES | 3 |
| SELECTED RESEARCH FINDINGS | 3 |
| TABLE 1 - Research Studies approved in 2011 | 7 |
| TABLE 2 - Research Studies closed in 2011 | 17 |
| | |
| APPENDICES | |
| Appendix A - Currently Open Schedule I and II Non-Human & Academic Human Studies | 25 |
| Appendix B - Currently Open Schedule II Clinical Drug Trial Studies | 31 |
| Appendix C - Currently Open Research Studies on the Treatment of Controlled Substance Abuse | 43 |
| Appendix D - Pertinent Sections - California Health and Safety Code | |
| § 11213 - Persons and researches using controlled substances | 45 |
| § 11480 & 11481 - Research Advisory Panel | 45 |
| § 11603 & 11604 - Attorney General | 46 |
| § 24172 - Experimental subject's bill of rights | 47 |
| § 24173 - Informed consent | 48 |

MEMBERS

RESEARCH ADVISORY PANEL OF CALIFORNIA

Edward P. O'Brien, J.D.
Panel Chairman
Appointed by Attorney General

Y. Jennifer Ahn, Pharm.D.
Executive Officer

Robert Quandt, Jr., Pharm.D.
Consultant

Andrew S. Kayser, MD, PhD
Appointed by the University of California at San Francisco
Designated University of California

John Mendelson, M.D.
Appointed by the California Medical Association
Designated professional medical society

Michele Pato, M.D.
Appointed by the University of Southern California
Designated private university

Laurence R. Upjohn, Pharm.D.
Appointed by the Department of Public Health

Sheri VanOsdol, Pharm.D.
Appointed by the State Board of Pharmacy

RAPC Website : www.ag.ca.gov/research

E-mail contact: jennifer.ahn@doj.ca.gov

This report represents a consensus among Panel members acting as individual experts. It does not represent policies or positions of the appointing agencies nor have those agencies been consulted by the Panel during its function or during the preparation of this report.

SUMMARY OF 2011 PANEL ACTIVITIES

During 2011 the Panel reviewed forty-three research study submissions. Forty-one were approved by the Panel. Among forty-one approved studies, eleven studies were Academic research studies, three studies were Substance Abuse Treatment research protocols, and twenty-seven studies were Clinical Drug Trial research protocols.

Thirty-seven research studies were completed or, in a few cases, terminated in 2011, and they were closed on the Panel's records.

At the end of 2011, the Panel was monitoring ninety-seven active research projects. Note Appendices A, B, and C for specific listings.

As part of the Panel's supervisory responsibility, ongoing projects are monitored by means of annual reports, Significant Adverse Event (SAE) reports and site visits. Approval may be withdrawn if the study deviates significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2011 and Table 2 is a list of the studies closed by the Panel in 2011.

SELECTED RESEARCH FINDINGS

Below are brief summary reports of several Panel approved projects which are of interest and indicative of the types of controlled substance research projects currently ongoing in California:

Titan Pharmaceuticals has announced positive results of six-month open-label safety retreatment study of probuphine titled "A Phase 3, Six-Month, Open-Label Re-Treatment Study of Probuphine™ in Opioid Addiction"

A total of 85 patients were enrolled at 18 sites with 67 subjects completing treatment. In California, 33 subjects were enrolled, 26 subjects completed the study, and 7 subjects withdrew early.

In this study, Probuphine was shown to be well tolerated, including the implant insertion and removal procedures, with a low incidence of adverse events and overall safety profile similar to that observed in the confirmatory Phase 3 study. Patients also reported a decreased use of illicit opioids, good control of opioid withdrawal and cravings and

high overall satisfaction with Probuphine. These data build upon the positive results of the Probuphine Phase 3 program reported to date and further support the company's preparation of a New Drug Application (NDA) for Probuphine.

Titan also provided an update on the preparation of the NDA for Probuphine, which it now plans to submit in the third quarter of this year. The company is on track to complete its analytical testing of Probuphine to provide additional Chemistry, Manufacturing and Control (CMC) data requested by the U.S. Food and Drug Administration (FDA) along with its preparation of the integrated clinical data, summary reports and electronic document preparation by mid-year. The manufacturing facility expansion and qualification for commercial scale production for Probuphine is in process, but has been slightly delayed due to longer than expected lead-time on air handling equipment and the manufacturing of three qualification batches is now expected to be completed in September.

Dr. Peggy Compton, RN, PhD, FAAN and colleagues at University of California, Los Angeles have provided the Panel with the following summary of research titled "Pain, Opioids and Pro-inflammatory Immune Responses"

The goal of our study is to evaluate inflammatory and immune responses to pain and/or opiate challenges in prescription opioid abusers (N=22, 11 female) and gender and age-matched healthy controls. To get the study underway and establish study procedures, we obtained UCLA IRB approval (MIRB3) for the healthy control group in June of 2010. To date, of the 163 potential healthy control subjects (78 females) responding to recruitment efforts, 45 (20 females) have been screened and 20 enrolled (9 females).

We submitted an amendment to include buprenorphine-maintained prescription opioid abusers (POAs) in December 2010 and were granted approval to enroll three POAs on May 26, 2011. IRB approval for the remaining eighteen POAs is contingent upon the IRB's satisfaction with the participation report of these initial 3 POAs. Since recruitment efforts began in July of 2011, we've had eight potential POA respondents (2 females), all of whom did not meet the initial eligibility criteria of being an opioid abuser or in a buprenorphine treatment program.

Decreased POA admission rates at the Integrated Substance Abuse Programs clinic was an initial barrier to our POA recruiting efforts. In August of 2011 the IRB approved expansion of our recruitment efforts to include SAMHSA-qualified opioid treatment centers (OTC) and private buprenorphine treatment specialist clinics in the greater Los Angeles area. Despite positive clinician response to our study objectives, we have yet to enroll a POA subject. Our colleagues have cited our exclusion criteria prohibiting participation of subjects with co-morbid DSM-IV diagnoses as a significant barrier to

recruitment; the clinical reality is that the majority of opioid abusers who present to treatment have a dual-diagnosis.

We continue to explore ways to boost recruitment and enrollment. Encouraged by the many positive clinician responses, we remain optimistic that we will reach our target of POAs by August 31, 2012.

Rhodes Pharmaceuticals has reported the status of the study titled "A Randomized, Parallel, Double-Blind Efficacy and Safety study of Biphentin™ Methylphenidate Hydrochloride Extended Release Capsules Compared to Placebo in Children and Adolescents 6 to 18 Years With Attention Deficit Hyperactivity Disorder"

Biphentin™ is designed to be a single, daily dose alternative to separate doses of immediate release methylphenidate by providing an extended release biphasic plasma profile. It distinguishes itself from similar extended release products on the market by achieving a first Cmax more similar to immediate release methylphenidate, which provides clinical advantages. It also comes in more strengths, eight, that allow better individualized dosing. Biphentin® was approved by Health Canada in March 2006 and launched in Canada in August 2006.

One California site was involved in this multi-center clinical trial at the University of California, Irvine Child Development Center. The UC Irvine site enrolled 29 subjects, and 24 subjects completed the 12-week study. The first subject was enrolled in January 2011. The clinical phase of the study concluded in November 2011.

The protocol provides for continuing compassionate use of the study drug following termination of the 12-week study. Currently approximately 14 patients continue to take the drug, one capsule a day. These patients are being monitored on a periodic basis.

TABLE 1
RESEARCH STUDIES
APPROVED IN 2011

| <u>PI/ Sponsor</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> |
|---|---|
| Hussien Al-Shamma, Ph.D. Arena Pharmaceuticals, Inc. San Diego, CA | Evaluation of lorcaserin for abuse liability using the Drug Discrimination Test in the Rat |
| Reese T. Jones, M.D. UCSF Drug Dependence Research Center San Francisco, CA | Phase I Study of Interactions between Oral Naltrexone and Bupropion and Intravenous Methamphetamine in Methamphetamine Experienced |
| Daniel Levin, Ph.D. Norac Pharma Azusa, CA | Evaluation of Cannabinoids derived from the Natural Product Marijuana |
| Sean Mackey, MD, PhD Stanford University Division of Pain Management Palo Alto, CA | Neural and Immune Effects of Short-term Opioid Use in Chronic Pain Patients |
| Ardis Ann Moe, M.D. UCLA Center for AIDS Research and Education Los Angeles, CA | Phase III, Placebo-Controlled, Double-Blind Crossover Study of Slow-Release Methylphenidate (Concerta™) for Treatment of HIV Dementia |
| Loten H. Parsons, Ph.D. The Scripps Research Institute. La Jolla, CA | Cognitive and Neurochemical Effects of Δ9-tetrahydrocannabinol and related cannabinoids in rodents |

Table 1 Cont.

Table 1 Cont.

| <u>PI / Sponsor</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> | <u>PI / Sponsor</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> |
|---|---|---|--|
| Matthew L. Springer, Ph.D. UCSF San Francisco, CA | Assessment of Impairment of Vascular Function in Rats by Environmental Exposure to Marijuana Second Hand Smoke | AcelRx Pharmaceuticals Redwood City, CA | A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg for the Treatment of Post-Operative in Patients after Open Abdominal Surgery (AcelRx IAP310) |
| Michael A. Taffe, Ph.D. The Scripps Research Institute La Jolla, CA | Behavioral and Physiological Toxicities of Cannabinoids | | |
| Michael A. Taffe, Ph.D. The Scripps Research Institute La Jolla, CA | Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs | AcelRx Pharmaceuticals Redwood City, CA | A Multicenter, Randomized, Open-Label, Parallel-Group Trial to Compare the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg to Intravenous Patient-Controlled Analgesia with Morphine for the Treatment of Acute Post-Operative Pain (AcelRx IAP309) |
| Ronald G. Victor, M.D. Cedars-Sinai Medical Center Los Angeles, CA | Cocaine and Sympathetic Nerve Activity in Humans - "Cocaine and the Heart" | | |
| Barth Wilsey, M.D. UC Davis Sacramento, CA | The Effect of Vaporized Cannabis on Neuropathic Pain in Spinal Cord Injury | Astra Zeneca / CRO - Quintiles Overland Park, KS | A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00004) |
| AcelRx Pharmaceuticals Redwood City, CA | A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab for the Management of Acute Pain Following Bunionectomy Alone or with Hammertoe Repair (AcelRx SAP202) | Astra Zeneca / CRO - Quintiles Overland Park, KS | A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00005) |

Table 1 Cont.

Table 1 Cont.

| <u>PI/ Sponsor</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> | <u>PI/ Sponsor</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> |
|---|--|---|--|
| Astra Zeneca / CRO - Quintiles Overland Park, KS | A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Relieving Opioid-Induced Constipation (OIC) in Patients with Cancer-Related Pain (AstraZeneca D3820C00006) | Johnson & Johnson PRD Malvern, PA | A Single-Dose, Open-Label, Randomized, Four-Way Crossover Study to Assess the Dose-Proportionality of the Pharmacokinetics of Tapentadol, Given as Tamper-Resistant Tablets, in Healthy Japanese and Korean Male Subjects (J & J PAI 1064) |
| Astra Zeneca / CRO - Quintiles Overland Park, KS | A Randomized, Double-Blind, Placebo-Controlled 12-Week Extension Study to Assess the Safety and Tolerability of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00007) | Mallinckrodt Inc / CRO - INC Middleton, WI | An Open Label Safety Study of COV795 in Subjects with Osteoarthritis or Chronic Low Back Pain (COV 15000181US) |
| Astra Zeneca / CRO - Quintiles Overland Park, KS | An Open-Label 52 week Study to Assess the Long-Term Safety of NKTR-118 in Opioid-Induced Constipation (OIC) in Patients with Non-Cancer-Related Pain (AstraZeneca D3820C00008) | Mallinckrodt Inc. Hazelwood, MD | A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of COV795 (Oxycodone HCl / Acetaminophen) ER Tablets in Moderate to Severe Post-Operative Bunionectomy Pain Followed by an Open Label Extension (COV 15000182US) |
| Astra Zeneca / CRO - Quintiles Overland Park, KS | An Open-label, Parallel-group, Phase I Study to Compare the Pharmacokinetics of NKTR-118 Following a Single-Oral Dose in Subjects with Renal Impairment and Subjects with Normal Renal Function (AstraZeneca D3820C00009) | Mundipharma / CRO - Parexel Woburn, MA | A Confirmatory, Placebo-Controlled, Randomized, Double-Blind, Single-Dummy, Parallel Group, Ratio-Finding Study in Constipated Pain Patients to Establish an Optimal Hydromorphone (Mundipharma HMX 3501) |

Table 1 Cont.

Table 1 Cont.

PI/ SponsorTitle of Study / Clinical Drug
Trial ProtocolNovartis Pharmaceuticals
East Hanover, NJ

A 6-Month, Open-Label Extension to a 40-Week, Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety study of Ritalin® LA in the Treatment of Adult Patients with Childhood-Onset ADHD (Novartis CRIT 124D 2302E1)

Purdue / CRO - PRA
Raleigh, NC

A Randomized, Double-blind, Placebo-controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy and Safety of Oxycodone/Naloxone Controlled-release Tablets (OXN) Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require Around-the-clock Opioid Therapy (Purdue ONU3701)

Purdue / CRO - Quintiles
Overland Park, KS

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy (Purdue ONU3704)

PI/ SponsorTitle of Study / Clinical Drug
Trial ProtocolPurdue / CRO - Quintiles
Overland Park, KS

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone/Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation with Require Around-the-clock Opioid Therapy (Purdue ONU3705)

Purdue / CRO - INC
Raleigh, NC

An Open-label, Multicenter Study to Assess the Long-Term Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Non-malignant and Non-neuropathic Pain (Purdue HYD3003)

Purdue / CRO - PRA
Charlottesville, VA

An Open-label, Extension Study to Assess the Long-Term Safety of Twice Daily Oxycodone Hydrochloride Controlled-release Tablets in Opioid Experienced Children Who Completed the OTR3001 Study (Purdue OTR3002)

Table 1 Cont.

Table 1 Cont.

| <u>PI / Sponsor</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> | <u>PI / Sponsor</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> |
|--|--|-------------------------------------|--|
| Purdue / CRO - INC Raleigh, NC | A Multicenter, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy and Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Low Back Pain (Purdue HYD3002) | Shire / CRO - ICON Brentwood, TN | Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD489-323) |
| Roxane / CRO - Quintiles Durham, NC | A Multicenter, Open Label, Safety and Pharmacokinetic Study of Oral Morphine Sulfate Administration in Pediatric Subjects 2 years old through 17 years old with Postoperative Pain (Roxane MORP-OS+T-(2-17)-SPK-1) | Shire / CRO - ICON Brentwood, TN | Phase 3, Open-label, Multicenter, 12-month Extension Safety and Tolerability Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Residual Symptoms or Inadequate Response Following Treatment with an Antidepressant (Shire SPD489-329) |
| Shire / CRO - Premier Research Bluff City, TN | A Phase 2, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Forced-Dose Titration Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults Aged 18-55 Years with Binge Eating Disorder (Shire SPD489-208) | Shire Pharmaceuticals Wayne, PA | A Phase 1, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Ascending, Multiple Oral Doses of SPD489 (Lisdexamfetamine Dimesylate) in Clinically Stable Adults with Schizophrenia (Shire SPD489-119) |
| Shire / CRO - ICON Brentwood, TN | Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD489-322) | | |

Table 1 Cont.

| <u>PI / Sponsor</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> |
|---|--|
| Shire Pharmaceuticals Wayne, PA | A Phase 2, Multicenter, Double-blind, Parallel-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD 489-209) |
| Lara Ray, Ph.D. UCLA Los Angeles, CA | Pharmacogenetics of Naltrexone for Methamphetamine Use Disorder |
| Steve Shoptaw, Ph.D. UCLA Dept of Family Medicine Los Angeles, CA | Varenicline for Methamphetamine Dependence |
| NIDA Rockville, MD | Cocaine Use Reduction with Buprenorphine (CURB) (NIDA CTN-0048) |

TABLE 2

RESEARCH STUDIES CLOSED OR
CANCELLED IN 2011

| <u>Sponsor / PI</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> |
|--|--|
| Gayle C. Baldwin, Ph.D. UCLA Los Angeles, CA | Methamphetamine Dependence: A Novel Laboratory Model |
| Giovanni Cucchiari, MD Childrens Hospital Los Angeles USC Keck School of Medicine Los Angeles, CA | Caudal versus Intrathecal Morphine for Post-operative Pain Control in Pediatric Patients |
| G. Patrick Dauert, M.D. UC Davis Medical Center Sacramento, CA | Does Oral Methadone Use in Opiate Replacement Therapy Prolong the QTc Interval? |
| Robert H. Edwards, M.D. Departments of Neurology and Physiology UCSF School of Medicine San Francisco, CA | Role of glutamate release by monoamine neurons |
| Frederick D. Frankel, Ph.D. UCLA Los Angeles, CA | Social Skills Training for Medicated Children |
| Jean Gehricke, Ph.D. UC Irvine Irvine, CA | The Reinforcing Mechanisms of Smoking in Adult ADHD |

Table 2 Cont.

| <u>Sponsor / PI</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> |
|--|--|
| Ian Gibbons, Ph.D. Theranos, Inc. Palo Alto, CA | Assay Development for Medical Device Submission to FDA |
| Scott Irwin, MD, PhD San Diego Hospice and Institute for Palliative Medicine San Diego, CA | An Open Label Trial of Methylphenidate for The Rapid Treatment of Depression in Hospice Patients |
| Thomas S. Kilduff, Ph.D. SRI International Menlo Park, CA | Neurobiological Studies of Gammahydroxybutyrate (GHB) |
| Thomas King, Ph.D. Alexza Pharmaceuticals Mt. View, CA | Development of an FDA Approved Dronabinol Pharmaceutical Product for Inhalation Delivery |
| Yuriy Kirichok, Ph.D. UCSF San Francisco, CA | Effects of Cannabinoids on Sperm Activity and Fertility |
| Edward T. Kisak, Ph.D. Fqubed, Inc. San Diego, CA | Transdermal Delivery of Tetrahydrocannabinol |
| Kimberly D. Lakes, Ph.D. UC Irvine Irvine, CA | The Effects of Vyvanse on Brain Hemodynamics and Reading |

Table 2 Cont.

| <u>Sponsor / PI</u> | <u>Title of Study / Clinical Drug Trial Protocol</u> |
|---|---|
| Stanley Parsons, Ph.D. UC Santa Barbara Santa Barbara, CA | Rapid Detection of 4-hydroxybutyrate |
| Mark Rollins, MD, PhD UCSF San Francisco, CA | Supplemental Oxygen: A Reduction in Pulse Oximetry Sensitivity or an Increased Margin of Safety? |
| Cephalon, Inc. Fort Washington, PA | A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Hydrocodone Bitartrate Extended-Release Tablets (CEP-33237) at 15 to 90 mg Every 12 Hours for Relief of Moderate to Severe Pain in Patients with Osteoarthritis or Low Back Pain Who Require Opioid Treatment for an Extended Period of Time (Cephalon C33237/3079). |
| Cephalon, Inc. Fort Washington, PA | A 12-Month, Open-Label Study to Evaluate the Long-Term Safety of Hydrocodone Bitartrate Extended-Release Tablets (CEP-33237) at 15 to 90mg Every 12 Hours in Patients Who Require Opioid Treatment for an Extended Period of Time (Cephalon C33237/3080) |
| Eli Lilly Pharmaceuticals Indianapolis, IN | A Fixed-Dose, Randomized, Double-Blind, Placebo-Controlled Study of LY2216684 in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (Lilly H9P-MC-LNBF) |

Table 2 Cont.

Sponsor / PITitle of Study / Clinical Drug
Trial Protocol

Insys Therapeutics
Phoenix, AZ

A Randomized, Double-Blind, Placebo-Controlled Multi-Center Study to Evaluate the Safety and Efficacy of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain
(Insys INS-05-001)

Ortho-McNeil Janssen Scientific Affairs
Titusville, NJ

A Placebo-controlled, Double-blind, Parallel-group, Individualized Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response with OROS Methylphenidate
(OMJA CONCERTA-ATT-3014)

Johnson & Johnson PRD
Horsham, PA

An Open-Label, Single-Ascending-Dose Study to Investigate the Pharmacokinetics and Safety of CONCERTA® in Healthy Japanese Adult Male Subjects
(J&J CONCERTANAP1003)

Johnson & Johnson PRD
Titusville, NJ

A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of JNJ-42160443 as Monotherapy in Subjects with Moderate to Severe, Chronic Knee pain from Osteoarthritis
(J & J PRD JNJ-42160443-PAI-2006)

Table 2 Cont.

Sponsor / PITitle of Study / Clinical Drug
Trial Protocol

King Pharmaceuticals
Cary, NC

A Multi-center, Primary Care-Based, Open-Label Study to Assess the Success of Converting Opioid-Experienced Patients, with Chronic, Moderate to Severe Pain, to EMBEDA™ Using a Standardized Conversion Guide, and to Identify Behaviors Related to Prescription Opioid Abuse, Misuse, and Diversion
(King ALO-01-10-4003)

Neuromed Pharmaceuticals
Conshohocken, PA

A Phase III, Flexible-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Osteoarthritis Pain
(Neuromed NMT1077-302)

Novartis Pharmaceuticals
East Hanover, NJ

A randomized, multi-center, double-blind, placebo-controlled, cross-over study evaluating the safety and efficacy of Focalin-XR 30 mg vs Focalin XR 20 mg as measured by SKAMP-Combined scores in children with Attention-Deficit Hyperactivity Disorder (ADHD) in a laboratory classroom setting
(Novartis CRIT 124 EUS 21)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

Ortho-McNeil Janssen Scientific Affairs
Irvine, CA

Double-Blind, Randomized, Placebo-
Controlled, Crossover Study Evaluating
the Academic, Behavioral and Cognitive
Effects of CONCERTA on Older Children
with ADHD (The ABC Study)
(OMJSA CONCERTA-ATT-4069)

Ortho-McNeil Janssen Scientific Affairs
Raritan, NJ

A Randomized, Double-Blind, Multi-
Center, Parallel-Group Study of
Tapentadol Immediate Release (IR) vs.
Oxycodone IR for the Treatment of
Subjects with Acute Post-Operative Pain
Following Elective Arthroscopic Shoulder
Surgery
(OMJSA R331333-PAI-3022)

QRxPharma / CRO - Rho, Inc.
Chapel Hill, NC

A Double-Blind, Randomized, Multi-
Center, Repeat-Dose, Comparison of the
Analgesic Efficacy & Safety of the Opioid
Combination Q8003 to each of the
Individual Milligram Components
(Oxycodone & Morphine) in the
Management of Acute Moderate to Severe
Pain Following Bunionectomy Surgery
(QRxPharma Q8003-021)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

QRxPharma / CRO - Rho, Inc.
Chapel Hill, NC

A Randomized, Double-Blind,
Multicenter, Repeat-Dose Comparison of
Q8003 to the Morphine-Equivalent Doses
of Oxycodone and of Morphine for the
Opioid-Related Adverse Events of
Nausea, Emesis, and Dizziness in Subjects
with Acute Moderate-to-Severe
Postoperative pain Following
Bunionectomy Surgery
(QRxPharma Q8003-022)

Shire / CRO - INC
Raleigh, NC

A Phase II, Multicenter Study with Open-
label and Randomized Double-blind
Placebo-Controlled Withdrawal Phases to
Evaluate the Efficacy, Safety, and
Tolerability of SPD489 in Adults with
Schizophrenia and Predominant Negative
Symptoms Who Are Clinically Stable and
Taking Stable Doses of Atypical
Antipsychotic Medication
(Shire SPD489-204)

Shire / CRO - INC
Raleigh, NC

A Phase 2, Multicenter, Randomized,
Double-blind, Placebo-controlled,
Parallel-group Study to Evaluate the
Efficacy, Safety, and Tolerability of
SPD489 in Adults with Clinically
Significant, Persistent Executive Function
Impairments (EFI) and Partial or Full
Remission of Recurrent Major Depressive
Disorder
(Shire SPD-205)

Table 2 Cont.

Sponsor / PI

Title of Study / Clinical Drug
Trial Protocol

APPENDIX A
CURRENTLY OPEN (through December 31, 2011)
SCHEDULE I AND SCHEDULE II
NON-HUMAN AND ACADEMIC HUMAN
RESEARCH STUDIES

Zogenix, Inc.
Emeryville, CA

A Randomized Double-Blind, Placebo-
Controlled Trial to Evaluate the Efficacy,
Tolerability and Safety of Hydrocodone
Bitartrate Controlled-Release Capsules in
Opioid-experienced Subjects with
Moderate to Severe Chronic Low Back
Pain.
(Zogenix ZX002-0801)

Principal Investigator

Title of Study

Mark A. Agius, M.D.
UC. Davis
Davis, CA

Cannabis for Spasticity/Tremor in MS:
Placebo Controlled Study

Gantt Galloway, Pharm.D.
APRL, CPMC Research Institute
San Francisco, CA

A Dose Ranging Study of Guanfacine for
Methamphetamine

Hussien Al-Shamma, Ph.D.
Arena Pharmaceuticals
San Diego, CA

Evaluation of lorcaserin for abuse liability
using the Drug Discrimination Test in the Rat

Walter Ling, M.D.
UCLA
Los Angeles, CA

Optimizing Outcomes Using Suboxone
for Opiate Dependence

Danielyn Angeles, Ph.D.
Loma Linda University
Loma Linda, CA

Panel Approved Research

Catalyst Pharmaceuticals
Coral Gables, FL

Vigabatrin for Treatment of Cocaine
Dependence: A Phase II Study"
(Catalyst CPP-01005)

Mariusz Banaszczyk, Ph.D.
Biosite Diagnostics
San Marcos, CA

Development of In-vitro Immunoassays for
the Detection of Abused Substances

Catalyst Pharmaceuticals
Coral Gables, FL

Vigabatrin for Treatment of
Methamphetamine Dependence: A Phase
II Study
(Catalyst CPP-02001)

Selena E. Barrett, Ph.D.
Ernest Gallo Clinic & Research Ctr.
Emeryville, CA

The role of cannabinoids and ibogaine in the
treatment of alcoholism and drug addiction

Titan Pharmaceuticals
S. San Francisco, CA

A Phase 3, Six-Month, Open-Label Re-
Treatment Study of Probuphine in Opioid
Addiction
(Titan PRO-811)

Matthias Behrends, M.D.
UCSF
San Francisco, CA

A Randomized, Parallel, Double-Blind
Efficacy and Safety Study of Biphentin™
Methylphenidate Hydrochloride Extended
Release Capsules Compared to Placebo in
Children and Adolescents 6 to 18 years with
Attention Deficit Hyperactivity Disorder

Appendix A Cont.

Appendix A Cont.

| <u>Principal Investigator</u> | <u>Title of Study</u> |
|---|--|
| Nancy E. Buckley, Ph.D. California State Polytechnic Univ. Pomona, CA 91768 | Panel approved research |
| John R. Cashman, Ph.D. Human BioMolecular Research Institute San Diego, CA | Molecular Evolution of Human Cocaine Catalysis |
| Kent S. Chu, Ph.D. YJ Bio-Products Cordova, CA | Immunochromatographic Test Device for THC and LSD |
| Laura Colin Biostride, Inc. Redwood City, CA | Panel Approved Research Project |
| Peggy Compton, RN, PhD UCLA School of Nursing Los Angeles, CA | Pain, Opioids, and Pro-inflammatory Immune Responses |
| Mark Geyer, Ph.D. UC San Diego San Diego, CA | Behavioral and Cytofluorimetric Studies of Psychoactive Drugs in Rats |
| Valerie Gruber, Ph.D. UCSF SF General Hospital San Francisco, CA | Investigation of Age Differences in Analgesic, Cognitive, and subjective effects of Oxycodone, Hydrocodone, and Acetaminophen |
| Kanthi F. Hettiarachchi, Ph.D. SRI International Menlo Park, CA | Analysis of Cannabinoids |

| <u>Principal Investigator</u> | <u>Title of Study</u> |
|--|---|
| Scott A. Irwin, MD, PhD San Diego Hospice/ Palliative Care San Diego, CA | Panel Approved Research Project |
| Reese Jones, M.D. UCSF San Francisco, CA | Phase I Study of Interactions between Oral Naltrexone and Bupropion and Intravenous Methamphetamine in Methamphetamine Experienced |
| Adam Leventhal, Ph.D. USC Keck School of Medicine Alhambra, CA | Influence of Genes and Emotions on medication Effects |
| Daniel Levin, Ph.D. NORAC Pharma Azusa, CA | Panel Approved Research |
| Daniel Levin, Ph.D. NORAC Pharma Azusa, CA | Panel Approved Research |
| Daniel Levin, Ph.D. NORAC Pharma Azusa, CA | Panel Approved Research |
| Daniel Levin, Ph.D. NORAC Pharma Azusa, CA | Panel Approved Research |
| Marie Lin, Ph.D. R.Ph. Lin-Zhi International, Inc. Sunnyvale, CA | Lin-Zhi Immunoassay Development Study |

Appendix A Cont.

| <u>Principal Investigator</u> | <u>Title of Study</u> |
|---|---|
| Edythe London, Ph.D. UCLA Los Angeles, CA | A Study to Assess the Cardiovascular, Cognitive, and Subjective Effects of Atomoxetine in Combination with Intravenous Amphetamine |
| Sean Mackey, MD, PhD Stanford University Palo Alto, CA | Neural and Immune Effects of Short-term Opioid Use in Chronic Pain Patients |
| Sean D. McAllister, Ph.D. CPMC Research Institute San Francisco, CA | Panel Approved Research Project |
| James T. McCracken, M.D. UCLA NPI Los Angeles, CA | An 8-Week, Randomized, Double-Blind Comparison of Twice-Daily Guanfacine, Once-Daily d-Methylphenidate ER (Focalin XR) and the Combination, with a 12 Month Open-Label Extension for the Treatment of ADHD in Pediatric Subjects Aged 7 to 14 years |
| John Mendelson, M.D. APRI/CPMC Research Institute San Francisco, CA | The Effects of MDMA on Sleep Architecture, Water Homeostasis, and Cognitive Function |
| John Mendelson, M.D. APRI/CPMC Research Institute San Francisco, CA | Bioavailability and Urinary Excretion of Oral L-Methamphetamine |
| Ardis Moe, Ph.D. UCLA Center for AIDS Research Los Angeles, CA | Phase III, Placebo-Controlled, Double-Blind Crossover Study of Slow-Release Methylphenidate (Concerta™) for Treatment of HIV Dementia |

Appendix A Cont.

| <u>Principal Investigator</u> | <u>Title of Study</u> |
|--|---|
| Loren Parsons, Ph.D. The Scripps Research Institute La Jolla, CA | Cognitive and Neurochemical Effects of Δ9-tetrahydrocannabinol and related cannabinoids in rodents |
| Richard Reznicek, M.D. Harbor-UCLA Medical Center Torrance, CA | A prospective, randomized, double-blind study comparing the efficacy and safety of intra nasal fentanyl spray to placebo as an analgesic in patients undergoing outpatient cystoscopic procedures |
| Rajkumar J. Sevak, Ph.D. UCLA Los Angeles, CA | Human Methamphetamine Self-Administration in a Progressive-Ratio Paradigm |
| Rajkumar J. Sevak, Ph.D. UCLA Los Angeles, CA | Safety and Initial Efficacy of Lisdexamfetamine for Modifying the Behavioral Effects of Intravenous Methamphetamine in Humans |
| Matthew L. Springer, Ph.D. UCSF San Francisco, CA | Assessment of Impairment of Vascular Function in Rats by Environmental Exposure to Marijuana Second Hand Smoke |
| Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA | Behavioral and Physiological Toxicities of Cannabinoids |
| Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA | Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs |

Appendix A Cont.

| <u>Principal Investigator</u> | <u>Title of Study</u> |
|--|--|
| Stephen Van Dien, Ph.D. Genomatica, Inc. San Diego, CA | Panel Approved Research Project |
| Ronald Victor, M.D. Heart Institute Cedars-Sinai Medical Center Los Angeles, CA | Cocaine and Sympathetic Nerve Activity in Humans - "Cocaine and the Heart" |
| Mark Wallace, M.D. UC San Diego San Diego, CA | Efficacy of Inhaled Cannabis for the Treatment of Painful Diabetic Peripheral Neuropathy |
| Jennifer L. Whistler, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA | Endocytosis and Opioid Receptors |
| Timothy Wigal, Ph.D. UC Irvine Irvine, CA | Brain Dopamine Function in Adults with Attention Deficit/Hyperactivity Disorder (ADHD) |
| Barth Wilsey, M.D. UC Davis Medical Center Sacramento, CA | The Analgesic Effect of Vaporized Cannabis on Neuropathic Pain |
| Barth Wilsey, M.D. UC Davis Medical Center Sacramento, CA | The Effect of Vaporized Cannabis on Neuropathic Pain in Spinal Cord Injury |

APPENDIX B

CURRENTLY OPEN (through December 31, 2011)
SCHEDULE II CLINICAL DRUG TRIAL STUDIES

| <u>Sponsor</u> | <u>Description or Title of Clinical Drug Trial Protocol</u> |
|---|---|
| AcelRx Redwood City, CA | A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab for the Management of Acute Pain Following Bunionectomy Alone or with Hammertoe Repair (AcelRx SAP202) |
| AcelRx Redwood City, CA | A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg for the Treatment of Post-Operative in Patients after Open Abdominal Surgery (AcelRx IAP310) |
| AcelRx Redwood City, CA | A Multicenter, Randomized, Open-Label, Parallel-Group Trial to Compare the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg to Intravenous Patient-Controlled Analgesia with Morphine for the Treatment of Acute Post-Operative Pain (AcelRx IAP309) |
| Astra Zenica / CRO - Quintiles Overland Park, KS | A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00004) |

Sponsor

Description or Title
of Clinical Drug Trial Protocol

Astra Zenica / CRO - Quintiles
Overland Park, KS

A Randomized, Double-Blind, Placebo-
Controlled Study to Assess the Efficacy and
Safety of NKTR-118 in Patients with Non-
Cancer-Related Pain and Opioid-Induced
Constipation (OIC)
(AstraZeneca D3820C00005)

Astra Zenica / CRO - Quintiles
Overland Park, KS

A Randomized, Double-Blind, Placebo-
Controlled Study to Assess the Efficacy and
Safety of NKTR-118 in Relieving Opioid-
Induced Constipation (OIC) in Patients with
Cancer-Related Pain
(AstraZeneca D3820C00006)

Astra Zenica / CRO - Quintiles
Overland Park, KS

A Randomized, Double-Blind, Placebo-
Controlled 12-Week Extension Study to
Assess the Safety and Tolerability of NKTR-
118 in Patients with Non-Cancer-Related Pain
and Opioid-Induced Constipation (OIC)
(AstraZeneca D3820C00007)

Astra Zenica / CRO - Quintiles
Overland Park, KS

An Open-Label 52 week Study to Assess the
Long-Term Safety of NKTR-118 in Opioid-
Induced Constipation (OIC) in Patients with
Non-Cancer-Related Pain
(AstraZeneca D3820C00008)

Astra Zenica / CRO - Quintiles
Overland Park, KS

An Open-label, Parallel-group, Phase I Study
to Compare the Pharmacokinetics of NKTR-
118 Following a Single-Oral Dose in Subjects
with Renal Impairment and Subjects with
Normal Renal Function
(AstraZeneca D3820C00009)

Sponsor

Description or Title
of Clinical Drug Trial Protocol

BRC Operations Pty Ltd.
Ultimo, NSW, Australia

International Study to Predict Optimized
Treatment in Attention Deficit/Hyperactivity
Disorder
(BRC iSPOT-A)

GW Pharmaceuticals
Mill Valley, CA

Panel Approved Research Project

GW Pharmaceuticals
Milly Valley, CA

Panel Approved Research Project

GW Pharmaceuticals
Milly Valley, CA

Panel Approved Research Project

INTRuST Clinical Consortium
La Jolla, CA

Randomized Controlled Trial of Galantamine,
Methylphenidate, and Placebo for the
Treatment of Cognitive Symptoms in Patients
with Mild Traumatic Brain Injury (mTBI)
and/or Posttraumatic Stress Disorder (PTSD)
("Cognitive REmediation After Trauma
Exposure" Trial = CREATE Trial)

Johnson & Johnson
Titusville, NJ

A Randomized-Withdrawal, Placebo-
Controlled, Study Evaluating the Efficacy,
Safety, and Tolerability, of Tapentadol
Extended-Release (ER) in Subjects with
Chronic, Painful Diabetic Peripheral
Neuropathy (DPN)
(J&J R331333-PAI-3027)

| <u>Sponsor</u> | <u>Description or Title of Clinical Drug Trial Protocol</u> |
|---|--|
| Johnson & Johnson Malvern, PA | A Single-Dose, Open-Label, Randomized, Two-Way Crossover Study to Assess the Bioequivalence of Tapentadol Given as Two 25mg Extended-Release Tamper-Resistant Formulation (TRF) Tablets Relative to One 50mg Extended-Release TRF Tablet in Healthy Japanese Male Subjects (J & J R331333 PAI 1062) |
| Johnson & Johnson Malvern, PA | A Single-Dose, Open-Label, Randomized, Two-Way Crossover Study to Assess the Bioequivalence of Tapentadol Given as Two 50mg Extended-Release Tamper-Resistant Formulation (TRF) Tablets Relative to One 100mg Extended-Release TRF Tablet in Healthy Japanese Male Subjects (J & J R331333 PAI 1063) |
| Johnson & Johnson Malvern, PA | A Single-Dose, Open-Label, Randomized, Four-Way Crossover Study to Assess the Dose-Proportionality of the Pharmacokinetics of Tapentadol, Given as Tamper-Resistant Tablets, in Healthy Japanese and Korean Male Subjects (J & J PAI 1064) |
| Mallinckrodt / CRO - INC Middleton, MD | An Open Label Safety Study of COV795 in Subjects with Osteoarthritis or Chronic Low Back Pain (COV 15000181US) |

| <u>Sponsor</u> | <u>Description or Title of Clinical Drug Trial Protocol</u> |
|--|--|
| Mallinckrodt Hazelwood, MD | A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of COV795 (Oxycodone HCl / Acetaminophen) ER Tablets in Moderate to Severe Post-Operative Bunionectomy Pain Followed by an Open Label Extension (COV15000182US) |
| Mundipharma / CRO - Parexel Woburn, MA | A Confirmatory, Placebo-Controlled, Randomized, Double-Blind, Single-Dummy, Parallel Group, Ratio-Finding Study in Constipated Pain Patients to Establish an Optimal Hydromorphone (Mundipharma HMX 3501) |
| Novartis Pharmaceuticals East Hanover, NJ | A 40-Week, Randomized, Double-Blind, Placebo controlled, Multicenter Efficacy and Safety Study of Ritalin® LA in the Treatment of Adult Patients with Childhood-Onset ADHD (Novartis CRIT124D2302) |
| Novartis Pharmaceuticals East Hanover, NJ | A 6-Month, Open-Label Extension to a 40-Week, Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety study of Ritalin® LA in the Treatment of Adult Patients with Childhood-Onset ADHD (Novartis CRIT 124D 2302E1) |

Sponsor

Purdue / CRO - PRA
Lenexa, KS

Purdue / CRO - PRA
Lenexa, KS

Purdue / CRO - PRA
Raleigh, NC

Description or Title
of Clinical Drug Trial Protocol

An Open-Label Study to Characterize the Pharmacokinetics and Safety of Oxycodone HCl q12h Controlled-Release (ORF) Tablets in Pediatric Patients Aged 6 to 16 Years Inclusive, Who Require Opioid Analgesia (Purdue OTR 1020)

An Open-Label, Multicenter Study of the Safety of Twice Daily Oxycodone HCl Controlled-Release Tablets in Opioid Experienced Children from Ages 6 to 16 Years Old, Inclusive, with Moderate to Severe Malignant and/or Nonmalignant Pain Requiring Opioid Analgesics (Purdue OTR 3001)

A Randomized, Double-blind, Placebo-controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy and Safety of Oxycodone/Naloxone Controlled-release Tablets (OXN) Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require Around-the-clock Opioid Therapy (Purdue ONU3701)

Sponsor

Purdue / CRO - Quintiles
Overland Park, KS

Purdue / CRO - Quintiles
Overland Park, KS

Purdue / CRO - INC
Raleigh, NC

Description or Title
of Clinical Drug Trial Protocol

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy (Purdue ONU3704)

A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone/Naloxone Controlled-release Tablets OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation with Require Around-the-clock Opioid Therapy (Purdue ONU3705)

An Open-label, Multicenter Study to Assess the Long-Term Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Non-malignant and Non-neuropathic Pain (Purdue HYD3003)

Sponsor

Purdue / CRO - PRA
Charlottesville, VA

Description or Title
of Clinical Drug Trial Protocol

An Open-label, Extension Study to Assess the Long-Term Safety of Twice Daily Oxycodone Hydrochloride Controlled-release Tablets in Opioid Experienced Children Who Completed the OTR3001 Study
(Purdue OTR3002)

Purdue / CRO - INC
Raleigh, NC

A Multicenter, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy and Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Low Back Pain
(Purdue HYD3002)

Rhodes Pharmaceuticals
Boston, MA

A Randomized, Double-Blind Study of the Time Course of Response of Biphentin® Methylphenidate Hydrochloride Extended Release Capsules As Compared to Placebo in Children 6 to 12 Years With Attention Deficit Hyperactivity Disorder in an Analog Classroom Setting
(Rhodes RP-BP-EF001)

Rhodes Pharmaceuticals
Boston, MA

A Randomized, Parallel, Double-Blind Efficacy and Safety Study of Biphentin™ Methylphenidate Hydrochloride Extended Release Capsules Compared to Placebo in Children and Adolescents 6 to 18 years with Attention Deficit Hyperactivity Disorder
(Rhodes RP-BP-EF002)

Sponsor

Roxane / CRO - Quintiles
Durham, NC

Description or Title
of Clinical Drug Trial Protocol

A Multicenter, Open Label, Safety and Pharmacokinetic Study of Oral Morphine Sulfate Administration in Pediatric Subjects 2 years old through 17 years old with Postoperative Pain
(Roxane MORP-OS+T-(2-17)-SPK-1)

Shire Pharmaceuticals
Hampshire, UK

A Phase III, Double-Blind, Placebo-Controlled, Randomized Withdrawal, Multicenter, Extension, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Children and Adolescents Aged 6-17 with Attention-Deficit/Hyperactivity Disorder (ADHD)
(Shire SPD489-326)

Shire Pharmaceuticals
Wayne, PA

A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults with Clinically Significant, Persistent Executive Function Impairments (EF) and Partial or Full Remission of Recurrent Major Depressive Disorder
(Shire SPD-205)

Shire / CRO - Premier
Buff City, TN

A Phase 2, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Forced-Dose Titration Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults Aged 18-55 Years with Binge Eating Disorder
(Shire SPD489-208)

Sponsor

Shire / CRO - ICON
Brentwood, TN

Description or Title
of Clinical Drug Trial Protocol

Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD489-322)

Shire / CRO - ICON
Brentwood, TN

Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD489-323)

Shire / CRO - ICON
Brentwood, TN

Phase 3, Open-label, Multicenter, 12-month Extension Safety and Tolerability Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Residual Symptoms or Inadequate Response Following Treatment with an Antidepressant (Shire SPD489-329)

Sponsor

Shire Pharmaceuticals
Wayne, PA

Description or Title
of Clinical Drug Trial Protocol

A Phase 1, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Ascending, Multiple Oral Doses of SPD489 (Lisdexamfetamine Dimesylate) in Clinically Stable Adults with Schizophrenia (Shire SPD489-119)

Shire Pharmaceuticals
Wayne, PA

A Phase 2, Multicenter, Double-blind, Parallel-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD 489-209)

Zogenix Inc.
Emeryville

A Long-Term Open-Label Safety Study of Hydrocodone Bitartrate Controlled-Release Capsules with Flexible Dosing to Treat Subjects with Moderate to Severe Pain (Zogenix ZX002-0802)

APPENDIX C

CURRENTLY OPEN (December 31, 2011) RESEARCH STUDIES
ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

| <u>Investigator or Sponsor</u> | <u>Description or Title of Research Study</u> |
|---|---|
| Leith E. Flower, M.D. PRL/CPMC Research Institute San Francisco, CA | A Pilot Trial of Naltrexone for Methamphetamine Addiction - Role of the A118G SNP |
| Grant P. Galloway, Pharm.D. PRL/CPMC Research Institute San Francisco, CA | A Dose Ranging Study of Modafinil for Methamphetamine Dependence |
| Leith Heinzerling, MD, MPH JCLA ISAP Los Angeles, CA | Pharmacogenomics and Medication Development for Methamphetamine Dependence |
| Leith Heinzerling, MD, MPH JCLA ISAP Los Angeles, CA | Pilot Trial of Bupropion versus Placebo for Methamphetamine Abuse in Adolescents |
| Walter Ling, M.D. JCLA ISAP Los Angeles, CA | Sustained-Release Methylphenidate for management of Methamphetamine Dependence |
| Jara Ray, Ph.D. JCLA Los Angeles, CA | Pharmacogenetics of Naltrexone for Methamphetamine Use Disorder |
| Steven Shoptaw, Ph.D. JCLA Los Angeles, CA | Phase I Safety Interaction Trial of Ibudilast with Methamphetamine |

Investigator or Sponsor

Steven Shoptaw, Ph.D.
UCLA
Los Angeles, CA

NIDA
Rockville, MD

Titan Pharmaceuticals / CRO - PPD
S. San Francisco, CA

Description or Title
of Research Study

Varenicline for Methamphetamine
Dependence

Cocaine Use Reduction with Buprenorphine
(CURB)
(CTN-0048)

A Randomized, Placebo and Active-
Controlled, Multi-Center Study of Probuphine
in Patients with Opioid Dependence
(Titan PRO-806)

APPENDIX D

SECTIONS CONCERNING THE RESEARCH ADVISORY PANEL
FROM THE CALIFORNIA HEALTH AND SAFETY CODE

§ 11213. Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to § 11480 and § 11481.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to § 11480 or § 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

§ 11480. The Legislature finds that there is a need to encourage further research into the nature and effects of marijuana and hallucinogenic drugs and to coordinate research efforts on such subjects.

There is a Research Advisory Panel which consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a private university in this State who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a statewide professional medical society in this state who shall be engaged in the private practice of medicine and shall be experienced in treating controlled substance dependency, a representative appointed by and serving at the pleasure of the Governor who shall have experience in drug abuse, cancer, or controlled substance research and who is either a registered nurse, licensed pursuant to Chapter 6 (commencing with § 2700) of Division 2 of the Business and Professions Code, or other health professional. The Governor shall annually designate the private university and the professional medical society represented on the Panel. Members of the Panel shall be appointed by the heads of the entities to be represented, and they shall serve at the pleasure of the appointing power.

The Panel shall annually select a chairman from among its members.

Appendix D Cont.

§ 11480. Cont.

The Panel may hold hearings on, and in other ways study, research projects concerning marijuana or hallucinogenic drugs in this state. Members of the Panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.

The Panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of marijuana or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of marijuana pursuant to § 11478.

The Panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of marijuana to the Attorney General.

The Panel shall report annually to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and, where available, the conclusions of the research project.

§ 11481. The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.

The Panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the chief of such approval. The Panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.

The Panel shall, annually and in the manner determined by the Panel, report to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and where available, the conclusions of the research project.

§ 11603. The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceedings to identify the individuals who are the subjects of research for which the authorization was obtained.

Appendix D Cont.

§ 11604. The Attorney General, with the approval of the Research Advisory Panel, may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

§ 24172. Experimental subject's bill of rights; contents

As used in the chapter, "experimental subject's bill of rights," means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in § 24175, this list shall include, but not be limited to the subject's right to:

- (a) Be informed of the nature and purpose of the experiment.
- (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
- (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
- (e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
- (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
- (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

Appendix D Cont.

§ 24172. Cont.

(i) Be given a copy of the signed and dated written consent form as provided for by § 24173 or § 24178.

(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

§ 24173. Informed consent

As used in this chapter, "informed consent" means the authorization given pursuant to § 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

(a) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by § 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.

(b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.

(c) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in § 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:

(1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.

Appendix D Cont.

§ 24173. Cont.

(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.

(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.

(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(5) An estimate of the expected recovery time of the subject after the experiment.

(6) An offer to answer any inquiries concerning the experiment or the procedures involved.

(7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.

(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.

(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.

(10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, "material" means ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.

Appendix D Cont.

§ 24173. Cont.

(d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in § 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by § 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.

Agenda Item 11

Attachment I

**Consumer Education Materials
Fact Sheets
Website Downloads 1/1/2012 to 12/31/2012**

| Name of Publication | Downloads (English) | Spanish | Chinese | Vietnamese |
|---|--------------------------------|----------------|----------------|-------------------|
| Generic Drugs | 2250 | 2820 | 888 | 826 |
| Bringing prescription drugs into the U.S. from foreign countries | 2112 | | | |
| Drug Discount Program | 2086 | 917 | 812 | 822 |
| Ever miss a dose of your medicine? | 2058 | 766 | 489 | 490 |
| Measuring Liquid Medicine | 1899 | | | |
| Do you understand the directions on RX medicine label? | 1858 | | | |
| Pill Splitting | 1816 | | | |
| Thinking of Herbals? | 1739 | 1369 | 559 | 515 |
| Tips to save you money when buying prescription drugs | 1129 | | | |
| Vaccinations and travel outside the U.S. | 1047 | | | |
| Antibiotics – a National Treasure | 983 | | | |
| Lower your drug costs | 924 | 805 | 799 | 842 |
| Counterfeit drugs | 660 | | | |
| Diabetes –Engage your health | 658 | 443 | 524 | 511 |
| What's the deal with double dosing? | 634 | 584 | 661 | 495 |
| What you should know before buying prescription drugs on the Internet | 583 | | | |
| Traveling Medicine Chest | 532 | | | |
| Is your medicine in the news? | 540 | 427 | 442 | 442 |

Agenda Item 11

Attachment 2

California State Board of Pharmacy

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Counterfeit Drugs

**Protect Yourself
from Fakes**



What are counterfeit drugs?

Counterfeit drugs are fake or copycat pharmaceutical drugs that are incorrectly labeled. Some may contain harmful, toxic substances that can cause dangerous health consequences, such as allergic reactions and side effects. Some may contain the wrong dose — or none at all — of the active ingredient. Either way, counterfeit drugs can keep you from getting the treatment you need and may cause your medical condition to get worse.

Where do counterfeit drugs come from?

Both brand name and generic drugs may be counterfeited. Counterfeit drugs can be manufactured anywhere in the world, although most of them originate in foreign countries where enforcement systems are lax. Some counterfeit drugs look so much like the real thing they can fool health professionals and patients alike. Even the labeling on the container may look identical to the real product.

What is being done to stop counterfeit drugs?

California is a pioneer in a nationwide system that will track and trace every pharmaceutical container that enters the state. The California State Board of Pharmacy developed the program known as e-pedigree to safeguard the drug supply and prevent counterfeit drugs from entering California. The program requires that every pharmaceutical container be scanned and tracked through each step of the supply chain, from the manufacturer to the pharmacy. The first phase of the program will begin in 2015, with full implementation expected by mid-2017.

What you can do now to minimize your risk

1. Use extra caution if you buy from Internet pharmacies

- If an Internet pharmacy doesn't list a physical address, don't buy from it. According to the World Health Organization, 50 percent of medicines bought on the Internet from sites that conceal their physical address are counterfeit.
- Avoid Internet pharmacies that offer a prescription drug based only on a questionnaire and without a prescription. You may receive an incorrect diagnosis or receive drugs that are expired, counterfeit or inappropriate for your condition. Under California law, it is illegal to dispense prescription drugs without a valid prescription, so these websites are breaking the law.

- All pharmacies that dispense drugs to patients in California, including Internet pharmacies, must be licensed by the California State Board of Pharmacy. If the pharmacy is located in another state but selling to California residents, it must be licensed in both its home state and California. You can check to see if the pharmacy is licensed by going to the California State Board of Pharmacy website, www.pharmacy.ca.gov. Simply click on 'Verify a License' and enter the name of the pharmacy.
- Check to make sure there is a Verified Internet Pharmacy Practice Sites (VIPPS) seal displayed on the website. This ensures that the pharmacy is licensed and the medicines they are selling are FDA-approved. For more information visit the VIPPS website, www.nabp.net.

2. Take an active role in your own safety

- Check the appearance of the medicine including its color, texture, and shape. If the medicine looks or tastes differently than the last time you had the prescription filled, tell your pharmacist immediately.
- Pay attention to the medicine container and the packaging to make sure it hasn't been altered in any way. If you suspect the packaging has been tampered with, contact the pharmacy where you bought the medicine or notify the California State Board of Pharmacy at the number listed on the back of this brochure. You may also notify the Food and Drug Administration by calling (800) FDA-1088 or going online to www.fda.gov/Drugs/DrugSafety/ucm170314.htm to file a report.

