



**California State Board of Pharmacy**

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

**Date: July 9, 2009**

**To: Communication and Public Education Committee**

**Subject: Presentation of Consumer Education Videos**

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At the California Pharmacists Association Outlook annual meeting in February 2009, the Pharmacy Foundation of California hosted a "film festival" of u-tube like videos dealing with such topics as don't share your medicine. These videos were produced by pharmacy students in California schools of pharmacy. The board's Executive Officer served as one of three judges in an "American Idol"-format.

There were about 20 of these videos produced, and they were clever, entertaining and educational.

At this meeting, we will show several of the award winners. The videos are short.

The committee may want to determine how it can assist in increasing the distribution and viewing of these videos.



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**Date:** July 9, 2009  
**To:** Communication and Public Education Committee  
**Subject:** Implementation of SB 472, Patient-Centered Prescription Container Labels

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Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. This statute requires the board to promulgate regulations for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011. The board is also directed to hold special public forums statewide in order to seek input from the public on the issue of prescription labels. **Attachment 1** contains a copy of SB 472.

The timeline envisioned for this process was:

- 2008: conduct public hearings statewide – six meetings were envisioned
- 2009: develop regulations and adopt the requirements by the end of the year
- 2010: pharmacies implement requirements to be ready for 1/1/11 implementation
- 2011: requirements become effective and labels on prescription medicine are compliant

The first special public forum was held at a community center in Fremont on April 12, 2008. Approximately 40 people attended, though most attendees were from the pharmaceutical industry.

The board has also convened special meetings of the subcommittee on November 20, 2008 at the Professionals Achieving Consumer Trust Summit in Los Angeles, on January 27, 2009 in San Diego, and in the evening of March 12 in Sacramento.

Three attendees at the initial forum were “public” participants. The vast majority of attendees at the next three meetings have not been consumers per se, but representatives of consumer groups or pharmacy stakeholders. Early on, it became apparent that the board would need to find alternative venues to increase participation from consumers.

### **1. Consumer Surveys Conducted by the Board of Pharmacy**

**Attachment 2**

In May 2008, board staff developed a prescription label survey for distribution at public outreach events. The survey is available in English and Spanish, and a copy is provided in **Attachment 2**.

Since late May 2008, board staff has been using the survey to interview attendees at public events. Consumers have been invited to complete surveys on-site during the events, or mail them to the board using the self-addressed envelopes provided. This method of soliciting information has proved less intimidating to consumers than individually speaking at public hearings. Board staff attending the community events has also reported positive feedback when discussing this initiative with the public. In October 2008, pharmacist and pharmacy associations agreed to share the surveys with their members to aid the board in data collection.

The survey can be completed and submitted electronically on the board's Web site at [https://app.dca.ca.gov/pharmacy/survey\\_sb472.asp](https://app.dca.ca.gov/pharmacy/survey_sb472.asp). It is also available on the board's Web site in Spanish. In addition, AARP invited consumers to "Put in Your Two Cents on Prescription Labeling" in the AARP September 2008 newsletter.

The board has also provided consumers with one-page fact sheets entitled, "Do you understand the directions on your Rx medicine label?" The fact sheet provides background information related to SB 472, and printed samples of faux prescription labels as a visual aid.

A total of 695 consumer surveys were completed board surveys as of July 7, 2009. **Attachment 2** also contains the results of the board's consumer surveys. Not every consumer provided an answer to each question, while others provided multiple answers to individual questions. Many consumers gave the same response (i.e., larger font) to more than one question.

Trends have been identified in the answers provided thus far. Many responses suggest that the purpose of the drug be printed on the prescription label, and that a larger or bolder type font be used.

When asked what would make prescription labels easier to read, the top two responses were:

- Larger or bolder print  
(347 of 578 responses = 60.0%)
- Highlighting directions for use and other information in colors other than black  
(65 of 578 responses = 11.3%)

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

- Print should be larger or darker  
(194 of 616 responses = 31.5%)

- No changes should be made to label – references were made to Target, Raley's, CVS and Kaiser labels  
(148 of 616 responses = 24.0%)
- Include purpose of the drug – state what condition the medication is intended to treat  
(71 of 616 responses = 11.5%)

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

- Directions for use  
(257 of 1,361 responses = 18.9%)
- Name of drug; if generic, brand name and generic  
(253 of 1,361 responses = 18.6%)
- Dosage prescribed  
(242 of 1,361 responses = 17.8%)

When asked for other suggestions, the top two responses were:

- Easy-open lids should be used; no child-proof caps for seniors  
(30 of 158 responses = 19.0%)
- Include purpose of the drug – state what condition the medication is intended to treat  
(22 of 158 responses = 13.9%)

In **Attachment 3** is a copy of the radio survey the board conducted with the Pharmacy Foundation of California early in 2009.

## **2. Status of SB 470**

This year, SB 470 (Corbett) would amend California Pharmacy Law by changing the requirements for prescription documents and prescription container labels also to contain the purpose of the medication if the prescriber and patient both desire that it appear on the label.

The addition of purpose to the label is an important component in preventing medication errors. It alerts the patient why he or she is taking the medication, and will alert the pharmacist to a possible medication error if there is an inconsistency in the purpose of a specific drug.

There has been only one Nay vote on this bill, which currently is awaiting a floor vote in the Assembly. If passed, it will go to the Governor for signature.

If enacted, any patient-centered label format should consider placement of purpose on the label.

# Attachment 1

*SB 472*

**Assembly Bill No. 472**

**CHAPTER 267**

An act to amend Sections 20751, 20752, 20754, 20755, 20756, 20757, 20758, 21563, and 21563.5 of the Food and Agricultural Code, relating to cattle brands, and making an appropriation therefor.

[Approved by Governor October 5, 2007. Filed with  
Secretary of State October 5, 2007.]

**LEGISLATIVE COUNSEL'S DIGEST**

AB 472, Committee on Agriculture. Cattle brands: fees.

Existing law establishes a system for recordation of cattle brands, and establishes various fees in connection with the recordation, and use of a brand, as specified. Existing law requires these fees to be deposited in the Food and Agriculture Fund, a continuously appropriated fund.

This bill would increase various fees in connection with recordation and use of cattle brands.

By increasing the amount of fees deposited in a continuously appropriated fund, this bill would make an appropriation.

Appropriation: yes.

*The people of the State of California do enact as follows:*

SECTION 1. Section 20751 of the Food and Agricultural Code is amended to read:

20751. The fee for each application for recording a brand is sixty dollars (\$60).

SEC. 2. Section 20752 of the Food and Agricultural Code is amended to read:

20752. The fee entitles the applicant to the recordation of one brand, one duplicate brand registration certificate, and the right to use the brand until the following April 1st. The fee for each additional duplicate is ten dollars (\$10).

SEC. 3. Section 20754 of the Food and Agricultural Code is amended to read:

20754. Except as otherwise provided in Section 20755, the owner of a brand shall, on or before April 30th after its recordation, pay to the bureau a biennial period renewal fee of sixty dollars (\$60) for the right to continue to use the brand.

SEC. 4. Section 20755 of the Food and Agricultural Code is amended to read:

20755. The owner of a recorded brand may, on or before April 30th of any year, pay in advance to the bureau a sum which is a multiple of sixty dollars (\$60). The payment entitles him or her to use the brand for a minimum of two years, but not to exceed 10 years, at the rate of thirty dollars (\$30) per year from and after April 1st of that year. If the advance payment is made, biennial renewals for the years within the period for which advance payment has been made are not required.

SEC. 5. Section 20756 of the Food and Agricultural Code is amended to read:

20756. If the right to use a brand is suspended for failure to pay the renewal fee, it may be reinstated within one year from the date of suspension upon the payment of the biennial renewal fee of sixty dollars (\$60) plus a twenty-five dollar (\$25) penalty fee.

SEC. 6. Section 20757 of the Food and Agricultural Code is amended to read:

20757. (a) Except as provided in subdivision (b), the fee for rerecording a forfeited or canceled brand shall be one hundred twenty dollars (\$120). This amount shall accompany the application to rerecord.

(b) When a penalty has been paid pursuant to Section 20222, within 30 days of the date the application to rerecord is received by the director, the fee to rerecord shall be sixty dollars (\$60).

SEC. 7. Section 20758 of the Food and Agricultural Code is amended to read:

20758. The fee for recording the transfer of a brand, including a new certificate, is sixty dollars (\$60).

SEC. 8. Section 21563 of the Food and Agricultural Code is amended to read:

21563. Except as otherwise provided in this article, the fee shall be paid at the point of inspection and is one dollar and forty-four cents (\$1.44) for each carcass or hide which is inspected.

SEC. 9. Section 21563.5 of the Food and Agricultural Code is amended to read:

21563.5. The fee for the inspection of each carcass or hide shall be one dollar and forty-four cents (\$1.44) for each carcass and hide originating in those counties or geographical areas where a point-of-origin inspection is maintained pursuant to Article 4 (commencing with Section 21141) of Chapter 6.

# Attachment 2

*Consumer Surveys  
Conducted for SB 472*

# 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 695 surveys were received as of July 7, 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** (257 of 1,361 responses = 18.9%)

**Name of drug; if generic, state generic name AND brand name** (253 of 1,361 responses = 18.6%)

**Dosage prescribed** (242 of 1,361 responses = 17.8%)

**Side effects/warnings/interactions/contraindications** (132 of 1,361 responses = 9.7%)

**Purpose of drug – state what condition medication is prescribed to treat** (87 of 1,361 responses = 6.4%)

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

**Print should be larger or darker** (194 of 616 responses = 31.5%)

**Nothing needs to be changed on the label** (148 of 616 responses = 24.0%)

**Include purpose of drug – state what condition medication is intended to treat** (71 of 616 responses = 11.5%)

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

**Larger or bolder print** (347 of 578 responses = 60%)

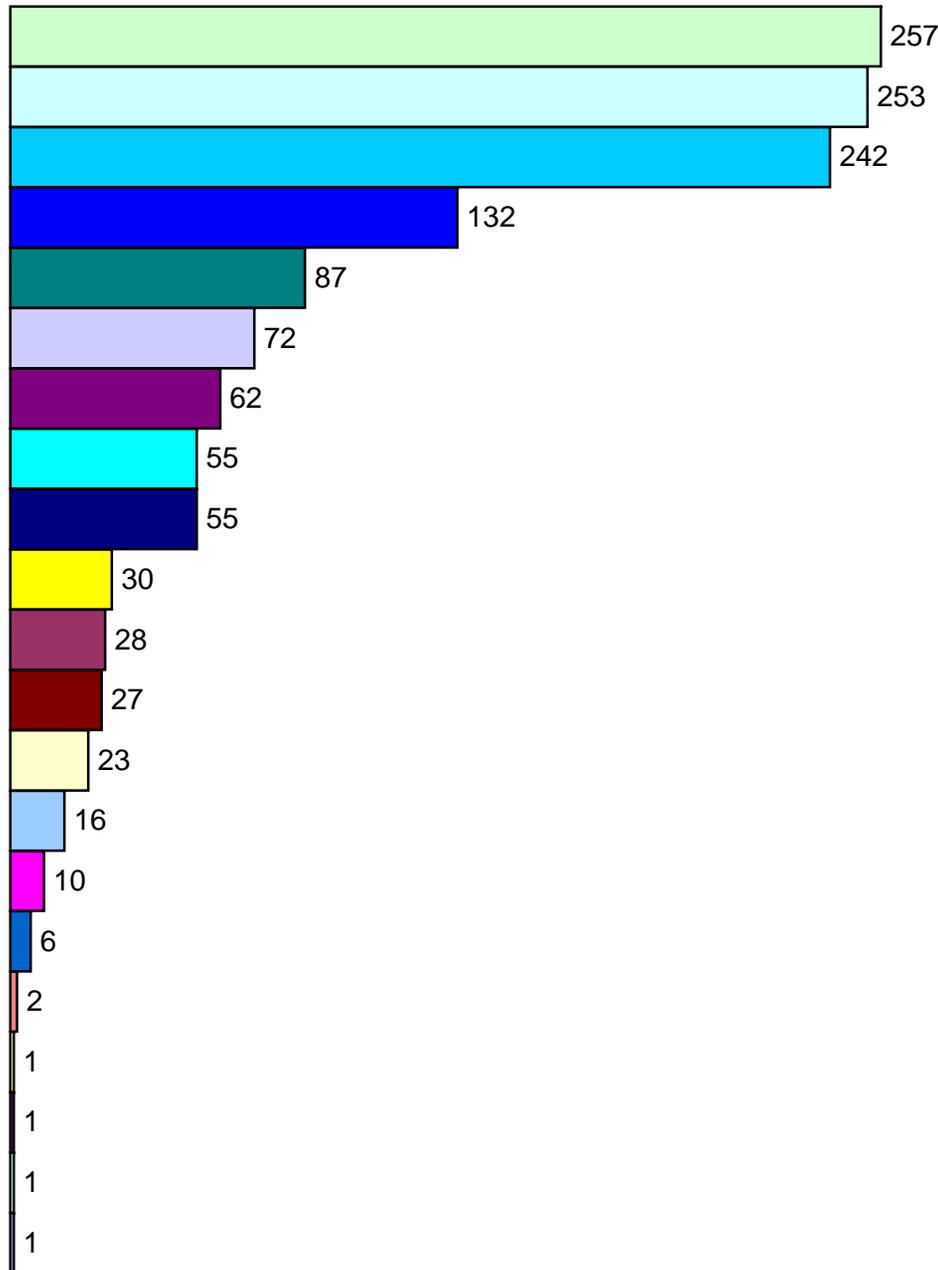
When asked for other suggestions, the top responses were:

**Easy-open lids/packages should be used; no child-proof caps for seniors** (30 of 158 responses = 19.0%)

**Include purpose of drug - state what condition medication is intended to treat** (22 of 158 responses = 13.9%)

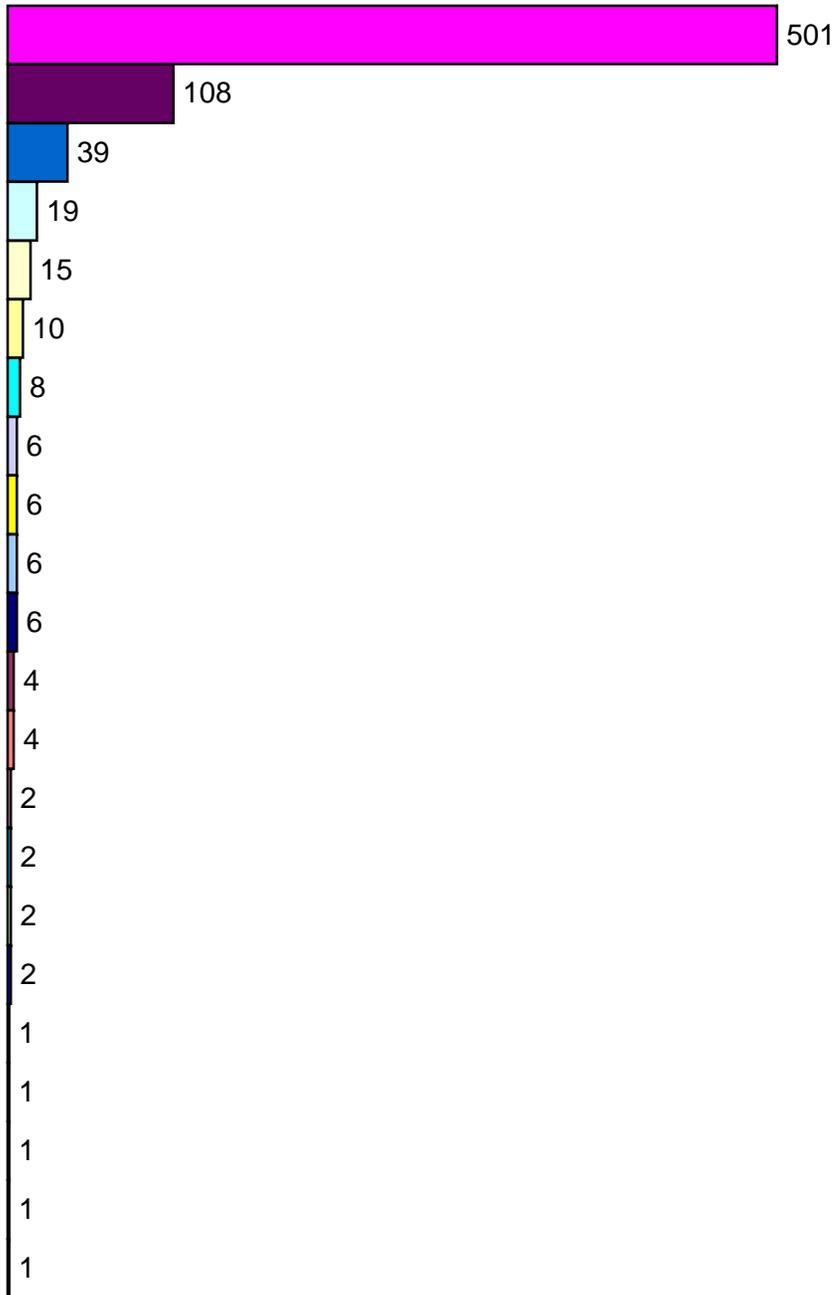
**CONCLUSIONS:** Most consumers participating in this survey strongly supported larger/bolder type font on prescription labels to increase readability. Many participants suggested that if a generic drug is provided, the prescription label should state the name of the generic drug name AND the brand-name it is generic for. Color printing and highlighting on labels was suggested to bring 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?**  
**695 surveys returned (1,361 responses to Question #1) as of July 7, 2009**



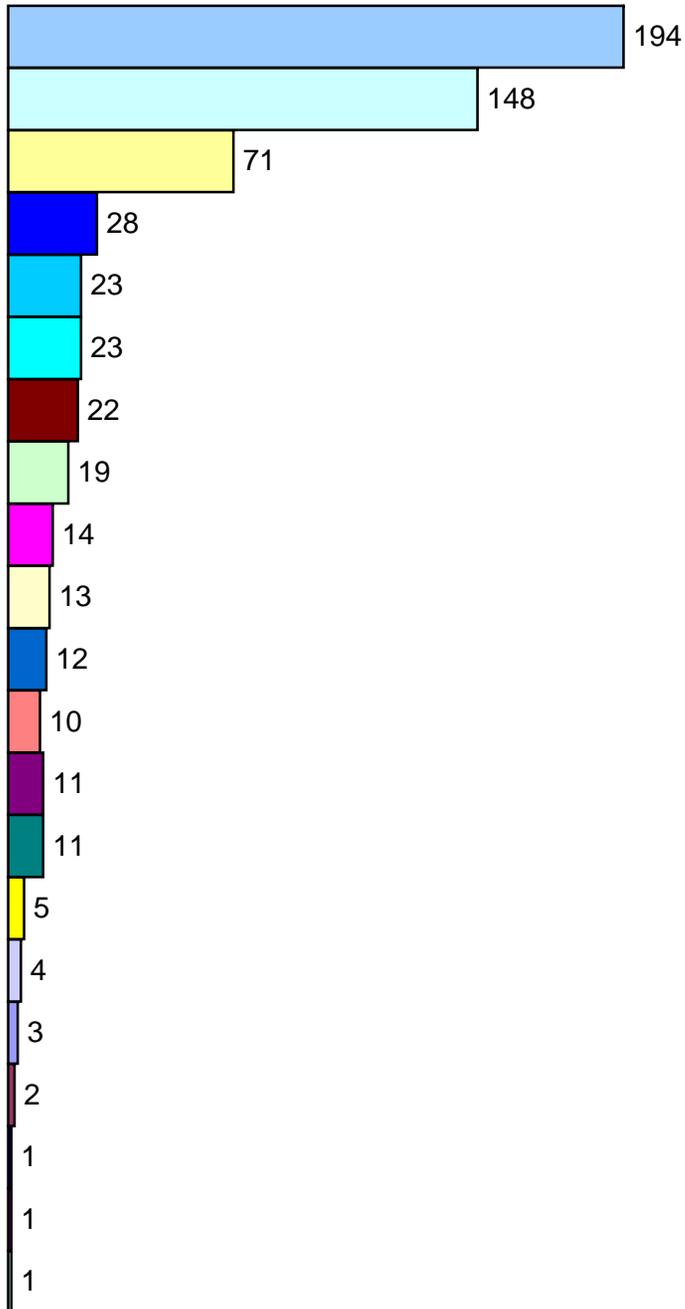
- Directions for use
- Name of drug; if generic, state generic name AND brand name
- Dosage prescribed
- Side effects/warnings/interactions/contraindications
- Purpose of drug; what condition medicine is intended to treat
- Specific times during day to take medicine (and with, w/o food)
- Refill renewal/reorder information/expiration; date filled
- Patient name (some also suggested patient's date-of-birth)
- Expiration date of drug
- Large or bold print
- Prescribing doctor's name and contact phone number
- Phone numbers (NOT printed in close proximity to each other)
- Description of pill (shape/color) or illustration
- Prescription number
- All information on label is important
- Name of drug store/pharmacy/pharmacist
- Diabetes information (1); batch number in case of recalls (1)
- With a large family, keep all prescriptions in the same place
- 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?**  
**695 surveys returned (745 responses to Question #2) as of July 7, 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
- Abbreviations should be eliminated
- 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
- I do not understand directions that only say "Take as directed"
- Bullets/spacing on label would be helpful; directions should be typed
- No long paragraphs; use fonts w/o serifs (such as Arial or Tahoma)
- Handout should be more readable; include NDC code
- Label from Kaiser understandable, label from Rite Aid not as clear
- 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

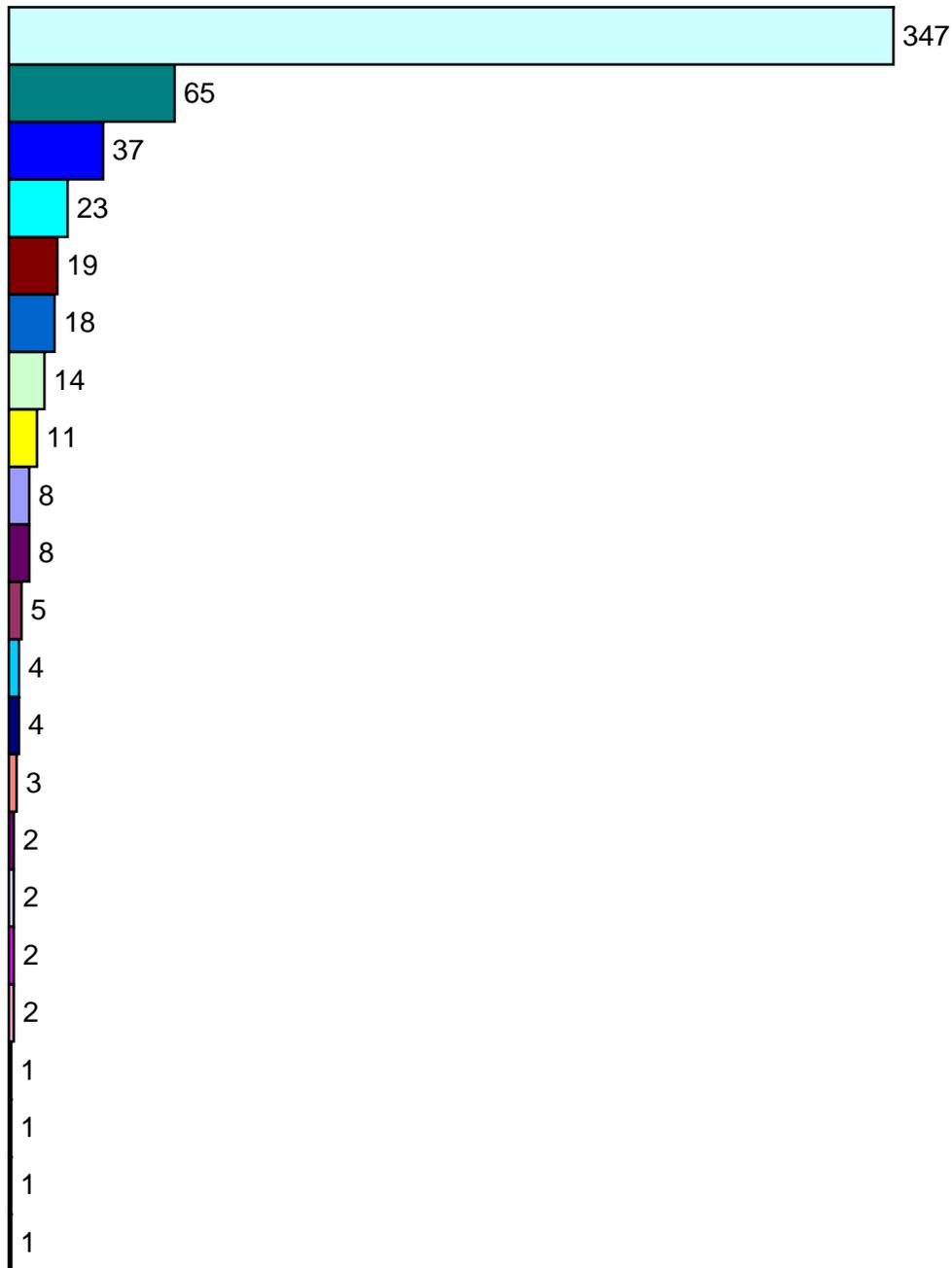
**QUESTION #3: What would you change on the prescription label?**  
**695 surveys returned (616 responses to Question #3) as of July 7, 2009**



- 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")
- Standardize location of info; uniform label; show information in same order
- Include direct phone numbers for easier communication with doctor/pharmacy
- Delete unneeded info (i.e., don't say take tab "by mouth" or show address)
- Print in patient's primary language; bilingual wording
- 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
- Label should (1 response) should not (1 response) refer patient to websites
- 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

## QUESTION #4: What would make the prescription label easier to read?

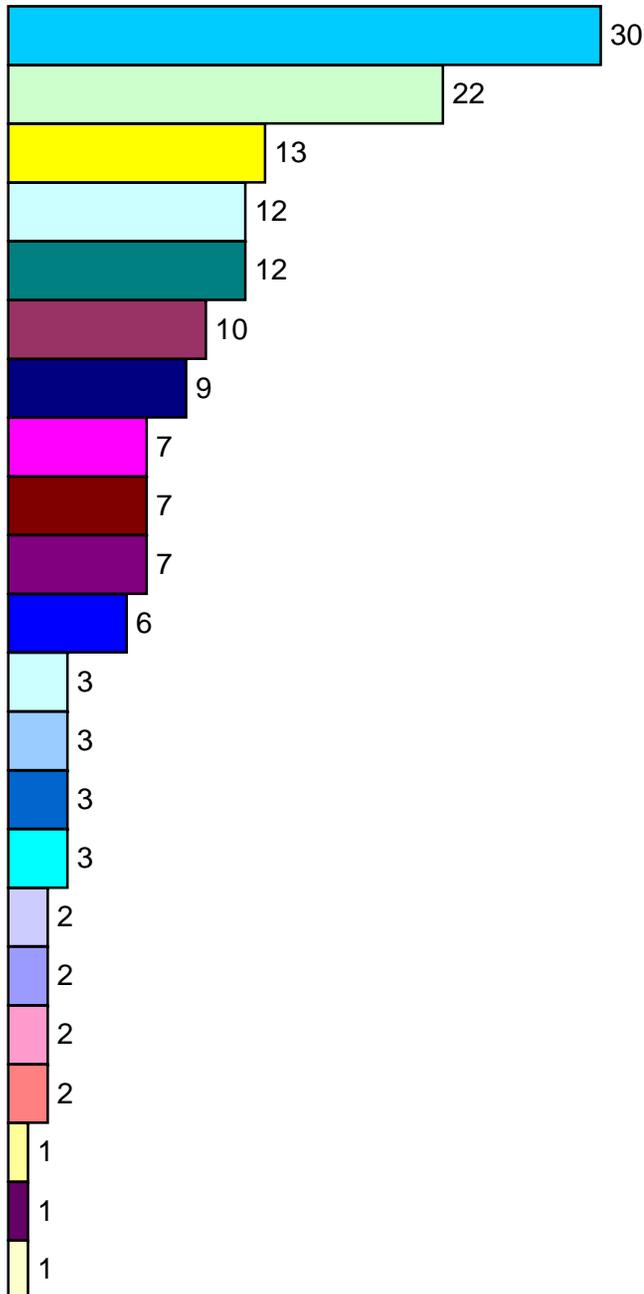
695 surveys returned (578 responses to Question #4) as of July 7, 2009



- Larger print (or bolder print)
- Highlighting directions & other info in colors (or color-coded label)
- Nothing
- Info should be in layman's terms; easy wording; don't abbreviate
- Bilingual wording
- Better description of directions (how/when to take; interactions)
- Eliminate clutter (i.e., multiple colors, icons, logos, name of PIC)
- Refill renewal information including renewal expiration date
- Increase container size so large labels can have large print
- Standard labeling for all pharmacies; standard placement of info
- Ink on label should not fade, disappear, smudge, rub off
- Underline info or separate directions for use into different lines
- Drawings would help or symbols (or chart of meds & time to take)
- Dark background with light/florescent print (or glow-in-the-dark)
- Yellow or white warning labels are easier to read than red
- Directions could be printed in all CAPS or bold
- Information on label should NOT be written by hand
- Lower/higher case letters easier to read than all caps; print clearly
- Beige background is easier for seniors to read than white
- List emergency phone number on label
- Standard placement of drug expiration date
- Print in braille for visually-impaired patients

## QUESTION #5: Other suggestions?

695 surveys returned (158 responses to Question #5) as of July 7, 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
- Put picture of pill on label or photo of pill or description of pill
- Make bottles rectangular or square w/flat surface and directions printed on long side
- Side effects/interactions should be stated (i.e., dry mouth may cause dental caries)
- 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)
- Different colored bottles or caps would help identify medications
- 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 when dose missed; pharmacist (foreign grads) must speak clearly
- Labels should be waterproof; labels should include barcodes to confirm correct drug
- Allow NP's name to appear on Rx bottle when submitting electronic prescriptions
- 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.)

# Attachment 3

*Radio Surveys Conducted  
with the Pharmacy  
Foundation of California*

The logo for the Pharmacy Foundation of California features a thick, black, curved line that starts on the left, arches over the text, and ends on the right. The text "Pharmacy Foundation" is in a large, bold, sans-serif font, and "of California" is in a smaller, bold, sans-serif font below it.

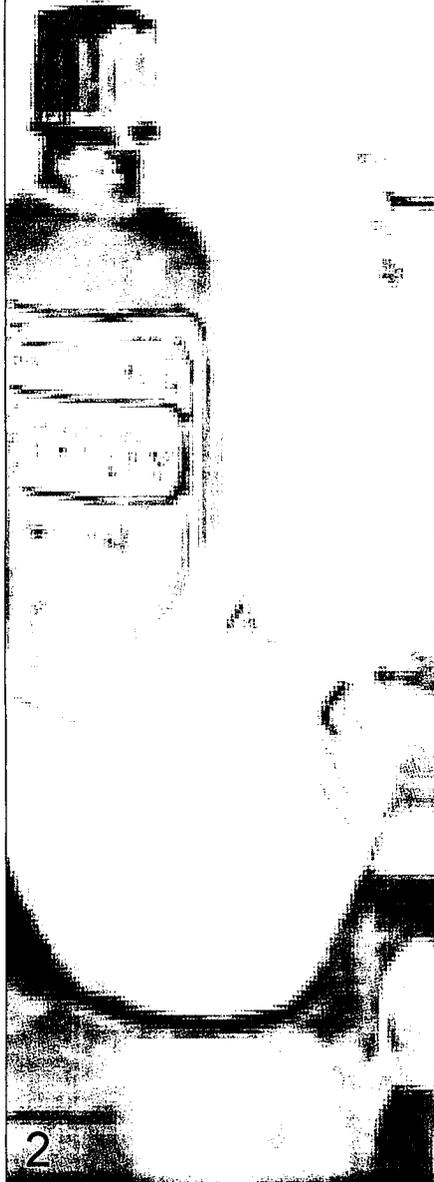
**Pharmacy Foundation**  
**of California**

# **Consumer Rx Label Survey**

**Michael J. Negrete, PharmD**

CEO, Pharmacy Foundation of California

[www.PharmacyFoundation.org](http://www.PharmacyFoundation.org)



# Survey Objective

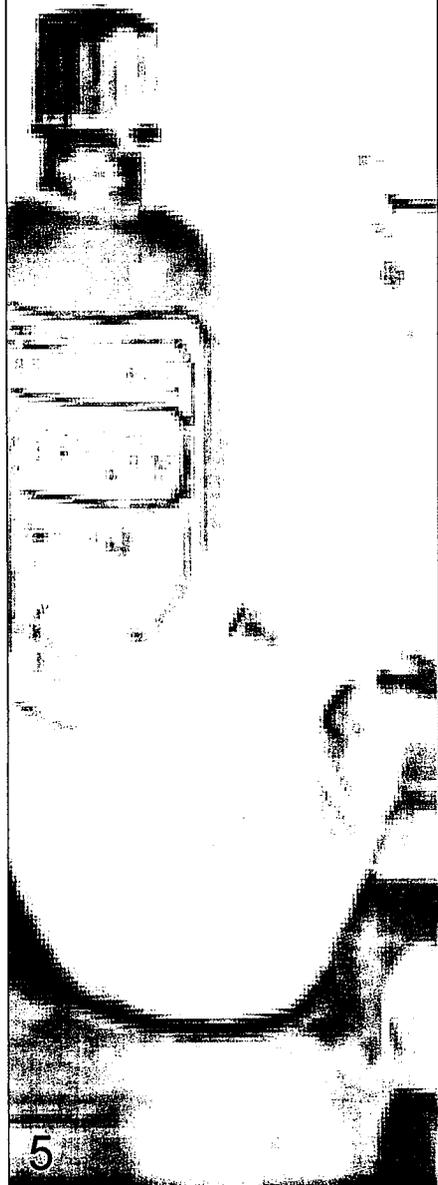
- To identify key attitudes, knowledge and behaviors of California consumers related to prescription drug labels

# Methodology

- Online survey distributed by Entercom broadcasting
  - One of the five largest radio broadcasting companies in the United States
  - Nationwide portfolio of 110 stations in 23 markets, including San Francisco, Boston, Seattle, Denver, Portland, Sacramento and Kansas City
- Survey made available during January '09 on radio station websites that stream their audio

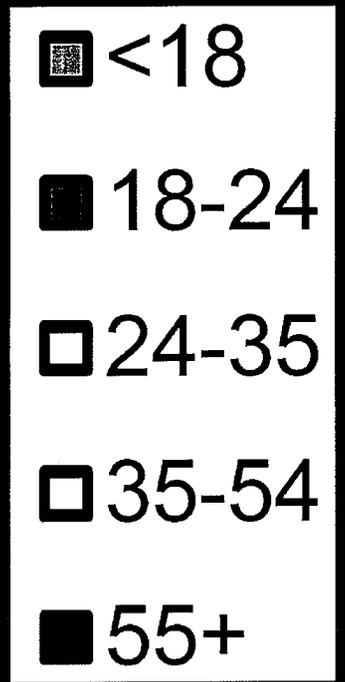
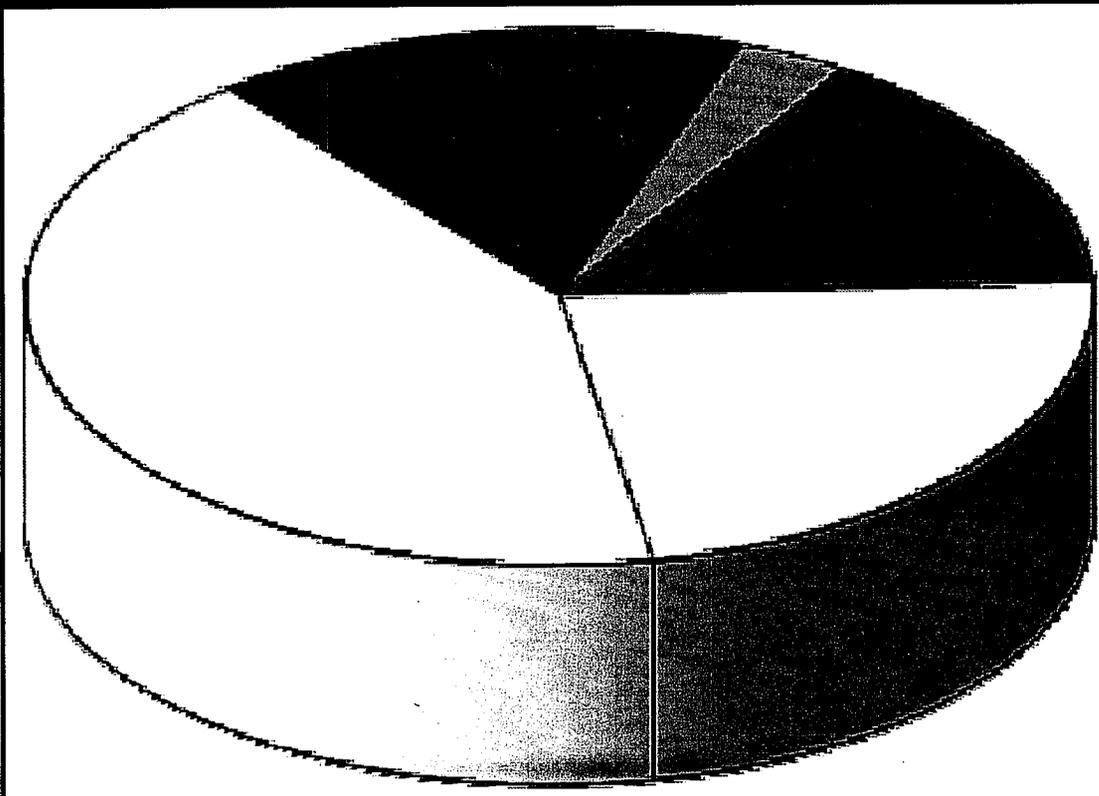
# Methodology

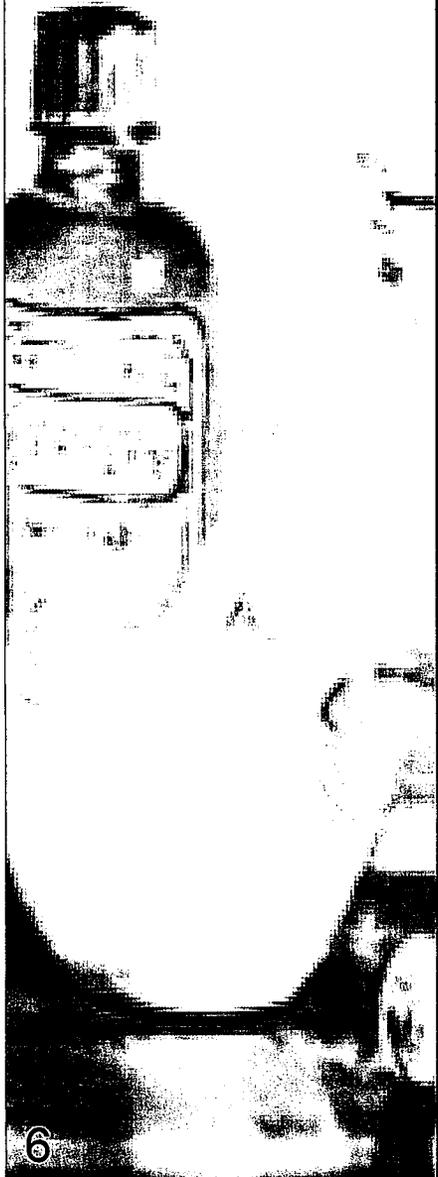
- Survey consisted of four questions:
  - How often do you read the label on your prescription containers?
  - When you need to obtain information from the label, what do you have the most trouble with?
  - Which parts of the label are most important to you?
  - What would you change on the prescription label to improve it?



# Results

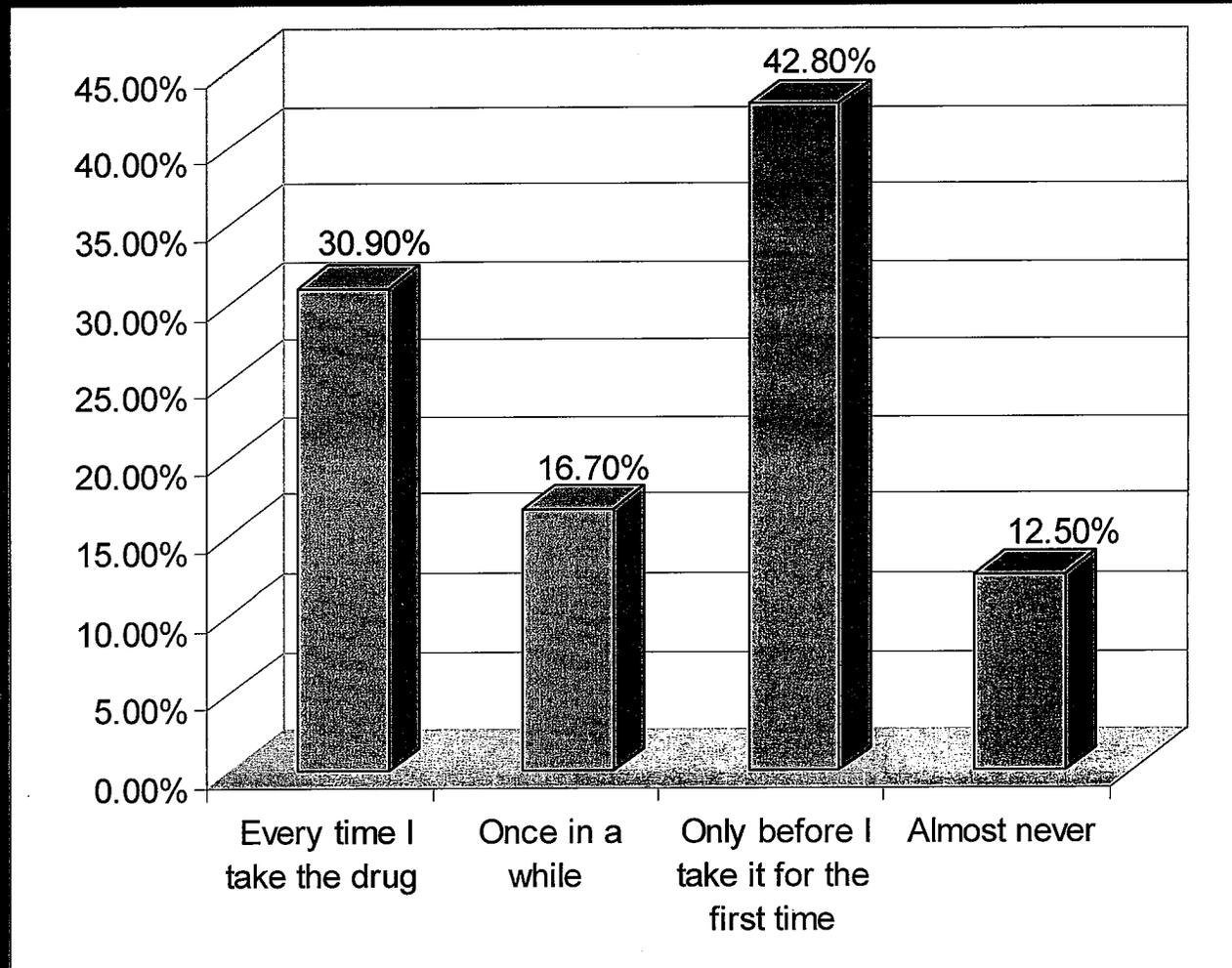
- 1,367 total responses
  - 59.6% female, 43.1% male
  - Age:

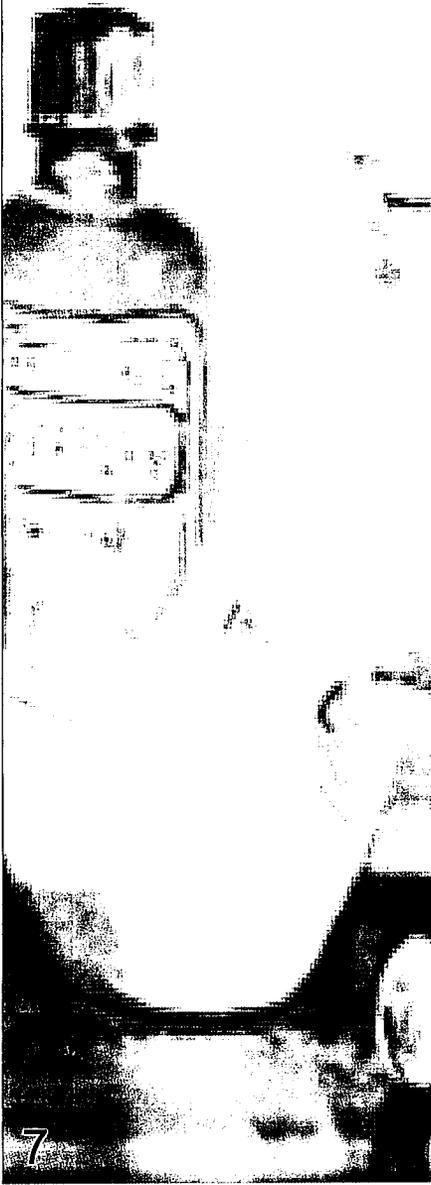




# Results

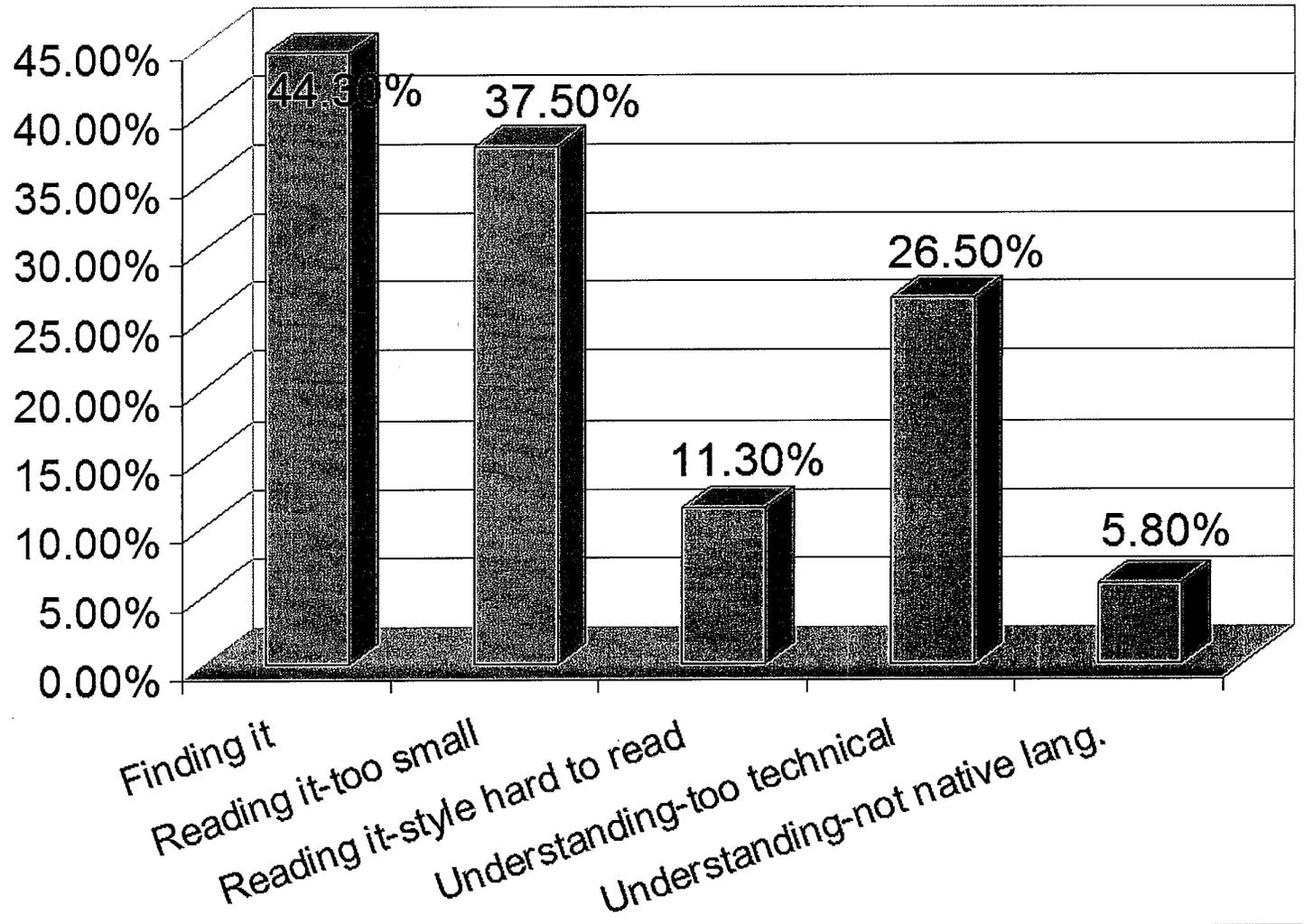
- How often do you read the label on your prescription containers?

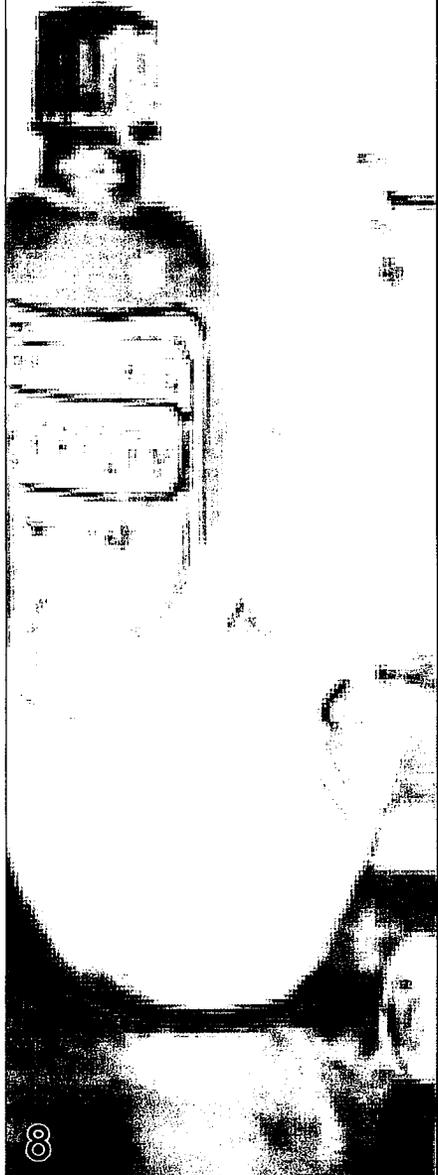




# Results

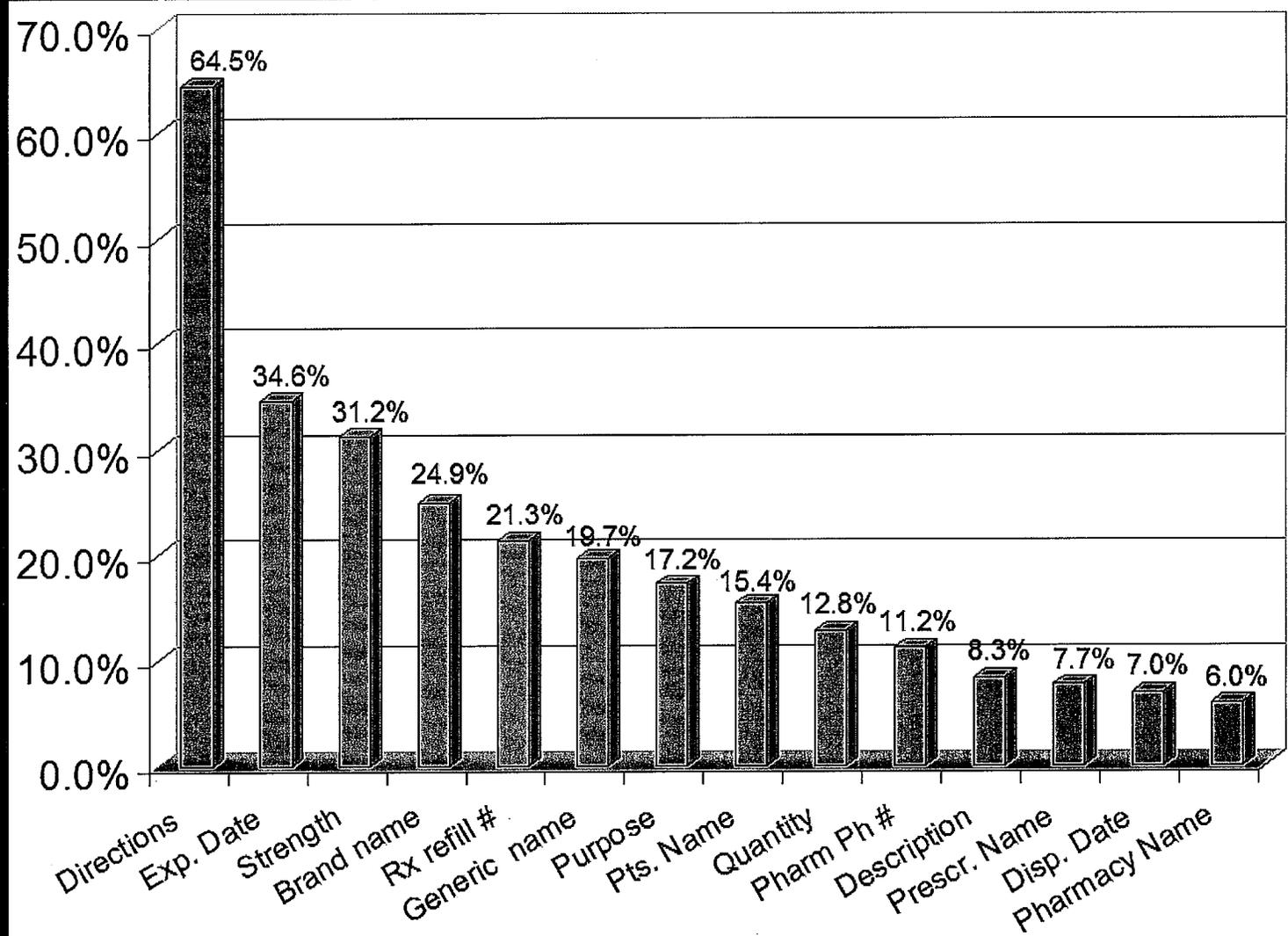
- When you need to obtain information from the label, do you have the most trouble:

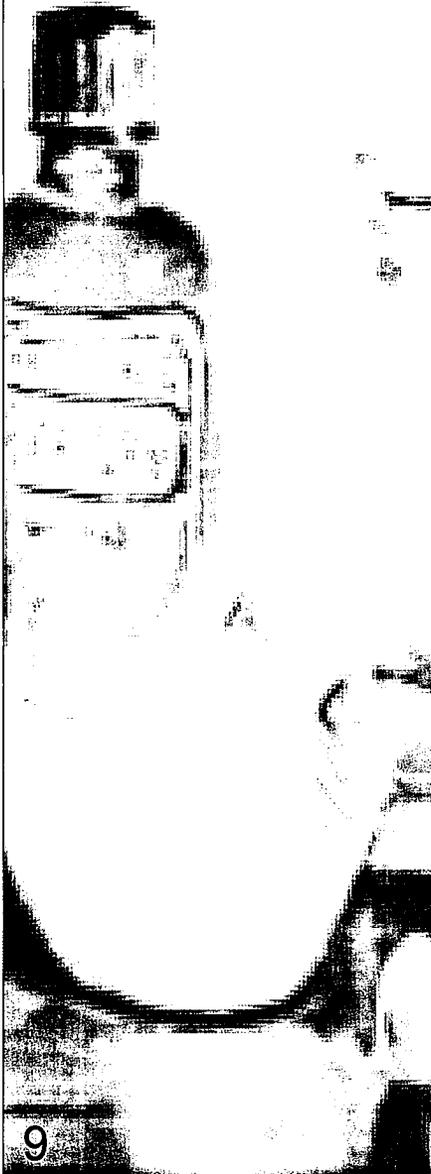




# Results

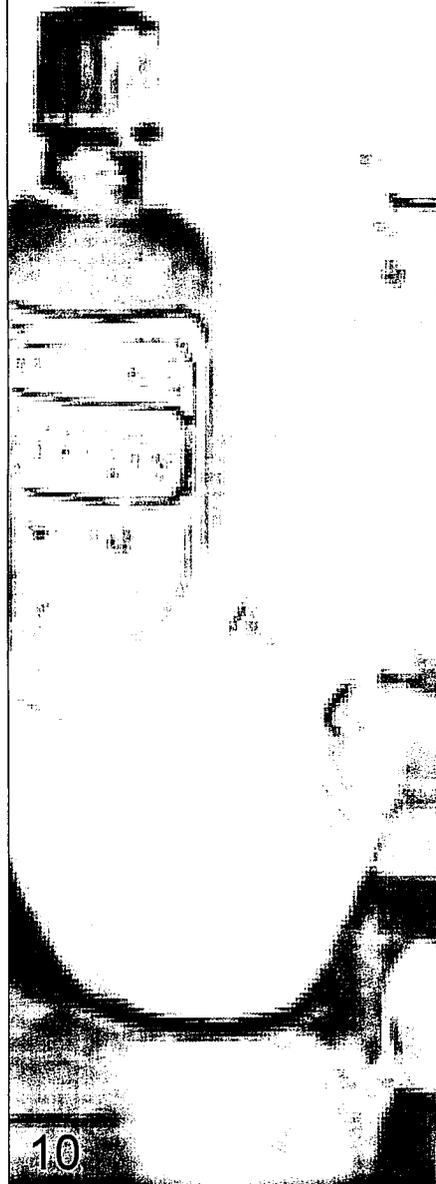
- Which parts of the label are most important to you?





# Discussion

- What would you change on the prescription label to improve it?
  - Bigger print/size
    - Drug name(s)
    - Directions
  - Clarity
  - Purpose
  - Side effects/interactions
    - On label vs. stickers
  - “Chunking” – Info should be laid out in identifiable sections



# Discussion

- Limitations
  - Representation of the sample
  - Reliability of self-reported information
- Need to encourage more frequent reading of the Rx label
- Label is crowded which requires things to be small & makes info difficult to find
- “Directions for use” is seen as particularly important



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DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 9, 2009**

**To: Communication and Public Education Committee**

**Subject: Informational Hearing of Draft Proposed Regulation Requirements to Mandate Patient-Centered Medication Container Labels Pursuant to SB 472 (Corbett, Chapter 470, Statutes of 2007)**

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During this meeting, the committee will hold an informational hearing on the regulation requirements to implement SB 472.

The board is directed by SB 472 to develop patient-centered prescription labels.

The board's executive officer will provide an overview of the steps taken by the board to develop the requirements.

1. Identification of Patient-Centered Elements on a Label

At the January 27, 2009 committee meeting, the committee reviewed each prescription label requirement specified in California Business and Professions Code section 4076 and selected those with the greatest importance to consumers.

The committee generated a basic list that identified three key items of most importance to a patient using a medication and the container's label:

- trade name/ generic name,
- directions
- strength

The complete assessment is provided in **Attachment 1**.

This information is supported by the data collected by the board in its consumer surveys.

Additionally, the board's executive officer has participated as a member of a National Association of Boards of Pharmacy (NABP) task force in developing model guidelines for patient-centered labels for all states. The results of this task force were shared at the NABP Annual Meeting in May 2009.

The Nap's list of key prescription label requirements from a patient's perspective is provided in **Attachment 2**, as is the full task force report.

The key recommendations of the task force report with respect to patient-centered labels are that: (page 49):

The task force agreed that the following information is critical and must appear on the label with emphasis (either highlighting or bolding) in a sans-serif font, with a minimum point size of 12, and which must never be truncated:

- patient name
- directions for use and, if included on the prescription drug order, the purpose/indication
- drug name and strength
- date by which the medication should be used

In developing California's regulation, the board will need to consider the general format of prescription container labels to maximize value to patients, and yet consider the diversity of containers in use by pharmacies. The NABP task force report on pages 4 and 5 show two sample labels that highlight essential consumer information and minimize other information. The board's staff also developed sample labels based on the elements identified as most important for consumers at the January meeting. These labels were shared at the March subcommittee meeting and are provided at the back of **Attachment 3**.

### **Directions for Use on Prescription Labels**

The board's staff has collected information about research in standardizing directions for use on prescription labels over the prior year. Standardizing the directions for use will be important for securing translations of the directions into key languages used in California. It is also important to assure that "take two tablets two times per day" appears consistently on the labels of medicine dispensed to patients.

One list of standardized directions is provided in **Attachment 4**. This list was developed by researcher Michael Wolf, PhD, who is an expert in the area of label design. Dr. Wolf attended the November 2008 forum held by the board on patient-centered labels and attended the April 2009 board meeting via telephone. Dr. Wolf states that about 90 percent of all directions for use will fit into one of these statements.

Standardizing the directions on labels was one component envisioned by the sponsors of SB 472.

### **FOR POSSIBLE ACTION: Discussion and Possible Action to Recommend Initiation of Rulemaking to Adopt 16 CCR Section 1707.5 Patient-Centered Prescription Container Labels**

At this meeting staff will distribute a draft of the proposed labeling regulation. The requirements and elements of a patient-centered label have been discussed at every

board meeting over the last 1.5 years. In the next few months, the board will need to finalize and adopt the requirements for patient-centered labels so that pharmacies will be able to modify their software to produce these labels on containers by January 1, 2011.

This will be the committee's opportunity to discuss whether the proposed language based on these discussions and from national research on improved labels that has been shared with the board is ready to be released for public comment as a prospective regulation for 45 days, or whether more work and refinement is necessary. If so, action at the Board Meeting on July 16 will be taken.

Comments from the public will also be taken.

Tomorrow, if the board believes the language as developed or amended during this meeting and the board meeting is sufficient to meet the requirements of SB 472, board action may be taken to initiate the rulemaking process. This would mean that the board could take action to adopt the regulation at the next board meeting (October 2009).

However, if the board desires more work on the proposed regulation, future meetings will be convened to refine the language for board approval and initiation of the rulemaking process at the next board meeting should occur. This will mean that the board could take action to adopt the regulation at the January 2010 board meeting.

# Attachment 1

## *Board-Determined Elements of a Prescription Container Label*



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

**Assessment of Components in California Business and Professions Code Section 4076  
Regarding Prescription Container Labels of Greatest Importance to Consumers**

List generated by the SB 472 Medication Label Subcommittee, January 27, 2009

**OF MOST IMPORTANCE:**

Trade Name/Generic Name  
Directions For Use  
Strength

**OTHER ELEMENTS REQUIRED:**

Patient's Name  
Prescriber's Name  
Pharmacy Name  
Pharmacy Address  
Prescription Number  
Quantity  
Expiration Date  
Condition  
Physical Description

# Attachment 2

## *NABP's Model Language for Patient-Centered Container Labels*

## Patient-Centered Information Focus of Task Force on Uniform Prescription Labels

Recognizing that prescription drug labels may currently require and highlight information pertinent for pharmacists rather than clearly displaying information critical to what the patient needs to know, the Task Force on Uniform Prescription Labeling Requirements agreed that major changes must be made to labels to ensure that information is provided in a uniform, patient-centered format. Keeping this in mind as they considered changes to prescription drug labeling, the task force, which met December 6, 2008, in Tucson, AZ, undertook the following charges.

1. Evaluate current state and federal laws and regulations addressing prescription label format and content.
2. Review the results of the findings of both state and federal studies regarding prescription labeling.
3. Study the feasibility of implementing standardized state requirements for prescription label format and content and for patient medication information.
4. Recommend revisions, if necessary, to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing these issues so as to increase readability

and comprehension of labels by patients. Early on in their discussions, the task force members agreed that it was important to create a clear, concise statement regarding the focus and purpose of their recommendations for prescription labeling. The members recommended that this statement be endorsed by the NABP Executive Committee and distributed to interested stakeholders. Through this statement, the task force members communicated their belief that labels should be used solely to provide patients with important information about medication use. The statement also in-

cluded the assertion that prescription labels should not replace critical pharmacist care responsibilities.

The task force members identified some critical pharmacist care responsibilities as (1) patient identification and (2) patient counseling. Patient identification encompasses patient data elements, such as the address. These elements are important identifiers for matching the prescription to the patient but do not warrant inclusion on the label, as this type of information should be contained in other patient identification systems. The task force members agreed that patient counseling is the single most effective component to increase and improve patient compliance and avoid medication errors. Because of this, they believe that prescription labels should be designed to supplement patient counseling, but not replace it in any way. Numerous studies cite 12-point, sans-serif fonts as providing the best readability; therefore, the task force members included this feature in its recommended amendments to the *Model Act* language addressing prescription drug labeling. Recognizing the relatively small

real estate afforded by 2" by 4" labels for prescription bottles, the task force identified critical information that should be presented in this larger, 12-point font versus important information for patients that could be provided in a smaller font size. Additionally, the task force identified several pieces of data, such as the pharmacy fax number, that could be removed from prescription drug labels because that information can be found through other sources and is not vital to patient safety.

The task force agreed that the following information is critical and must appear on the label with emphasis (either highlighting or bolding) in a sans-serif font, with a minimum point size of 12, and which must never be truncated:

- Patient name
- Directions for use and, if included on prescription drug order, the purpose/indication
- Drug name and strength
- Date by which the medication should be used

The task force also recommended that the following information be included in the *Model Act* as mandatory data elements for labels, but that this data should not supersede the aforementioned

critical information in size or emphasis.

- Pharmacy name
- Pharmacy telephone number
- Prescriber name
- Fill date (the date the prescription was dispensed)
- Prescription number
- Drug quantity
- Number of refills
- Product description
- Auxiliary information

In addition, the task force recommended the *Model Act* be amended to note that the following additional data elements may appear on the prescription label:

- Bar codes
- Pharmacy address
- Pharmacy store number

Through its discussions on which information should be included on prescription labels, the task force recognized that its recommendations represent a significant change in the philosophy of what defines a prescription label and the purpose of the prescription label. Because the *Model Act* is not intended to contravene state and federal laws or regulations, the task force supports NABP working with relevant agencies and organizations to allow implementation of the patient-centered label the task force developed.

Finally, the task force also recommended

that NABP work with the American Medical Association, the Federation of State Medical Boards, the Centers for Medicare and Medicaid Services, and other relevant organizations to require that medication indications be included on written and electronic prescription drug orders. The task force members discussed how providing on a prescription the purpose for which a drug was prescribed is an important tool for protecting patients. With this tool, pharmacists can better counsel patients on how and why they are taking the medication. This concept has a history of support among NABP members as evidenced by NABP Resolution No. 100-7-04, Medication Indication on the Prescription, which was passed by the membership at its Annual Meeting in 2004; the task force members felt that with the profession's focus on patient-centered labels that the time was well suited to pursuing this change.

The recommendations of the task force were approved by the NABP Executive Committee during its February 2009 meeting. The full report of the task force is available on the NABP Web site at [www.nabp.net](http://www.nabp.net) under News/Press. ®



## Report of the Task Force on Uniform Prescription Labeling Requirements

### Members Present:

Michael J. Romano (PA), *chair*; Barry J. Boudreaux (NV); Karen DiStefano (RI); Patricia Donato (NY); Virginia Herold (CA); Ronald Huether (SD); William Prather (GA); Leo H. Ross (VA)

### Others Present:

Karen M. Ryle, *executive committee liaison*; Carmen Catizone, Melissa Madigan, Larissa Doucette, *NABP staff*

### Guests:

Colleen Brennan, *United States Pharmacopeia*; Darren K. Townzen, *National Council for Prescription Drug Programs*

The Task Force on Uniform Prescription Labeling Requirements met December 6, 2008 at the JW Marriott Starr Pass Hotel, Tucson, AZ.

This task force was established in response to Resolution 104-3-08, Task Force on Uniform Prescription Labeling Requirements, which was approved by the NABP membership at the Association's 104<sup>th</sup> Annual Meeting in May 2008.

### Review of the Task Force Charge

Task force members reviewed their charge and accepted it as follows:

1. Evaluate current state and federal laws and regulations addressing prescription label format and content.
2. Review the results of the findings of both state and federal studies regarding prescription labeling.
3. Study the feasibility of implementing standardized state requirements for prescription label format and content and for patient medication information.
4. Recommend revisions, if necessary, to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (*Model Act*) addressing these issues so as to increase readability and comprehension of labels by patients.

**Recommendation 1: Endorse and disseminate statement on prescription labeling.**

The task force recommends that the NABP Executive Committee endorse the following statement on the issue of prescription labeling and disseminate it to all interested stakeholders:

The purpose of the prescription label is to provide critical information to the patient so that he or she may use the medication appropriately and comply with the medication regimen. The label should be patient-centered. The label should not be used as an audit mechanism by third-party payers, nor should it be used for promotional purposes by dispensing pharmacies. Further, the label should not be used as a sole means to determine compliance with pharmacy laws and regulations by pharmacy regulators.

The prescription label cannot and should not replace critical pharmacist care responsibilities, such as appropriately identifying the patient at the time of dispensing and providing patient counseling.

**Background:**

Upon review and discussion of the issue of prescription labeling and concerns related to patients' understanding of such labeling, the task force determined it is important to clearly identify for what purposes prescription labels should and should not be used. As stated above, members felt that labels should be used solely to provide patients with important information about medication use. They agreed that prescription labels should not replace critical pharmacist care responsibilities. Identified were two such primary responsibilities: patient identification and patient counseling. On these issues, the task force stated the following:

1. Patient Identification – Patient data elements, such as address, are important identifiers but do not warrant inclusion on the label; instead, such information should be contained in other patient identification systems upon which a pharmacist relies to ensure that the patient receives his or her medication and to avoid confusion among patients with similar names or whose names may bear suffixes such as “Jr” or “Sr” within a family group.
2. Patient Counseling – The single most effective component to increase and improve patient compliance and avoid medication errors, as documented in numerous studies, is appropriate patient counseling. The prescription label is designed to supplement this critical pharmacist responsibility and not replace it in any way. Pharmacists cannot avoid their legal and professional responsibilities by deferring counseling activities to the prescription label. Further, boards of pharmacy cannot regulate counseling activities through the prescription label.

**Recommendation 2: Amend the NABP Model Act language addressing prescription drug labeling.**

The task force recommends that NABP Executive Committee approve amendments to the *Model Act* that will ensure prescription labels are organized in a patient-centered manner and that mandate the following data elements appear on the prescription label. The task force has consciously removed some data elements historically included on prescription labels to make room for the most critical patient information.<sup>1</sup>

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<sup>1</sup> Insert examples of recommended labels

- A. Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif (such as “arial”), minimum 12-point font, and in “sentence case.” Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated.
- a. Patient name.
    - i. Legal name of the patient. If patient is an animal, include the last name of the owner, name of the animal, and animal species.
  - b. Directions for use.
    - i. The directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order.
      - 1. Boards of pharmacy and licensees should recognize that “take as directed” may not provide sufficient information for the appropriate use of the medication. “Take as directed” is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. “Take as directed” should not be used in lieu of patient counseling.
      - 2. It is understood that prescription drug orders often do not include the indication for use.
    - ii. Language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.
  - c. Drug name.
    - i. Name of the drug.
    - ii. If written for a brand name and a generic drug is dispensed, include phrase “Generic for [brand name].”
    - iii. If a fixed combination generic product is dispensed, use the United States Pharmacopeia (USP) publication of Pharmacy Equivalent Names (PEN) abbreviation. If no PEN has been officially issued by the USP, label the medication *secundum artem*.
    - iv. Include drug name suffixes, such as CD, SR, XL, XR, etc.
  - d. Drug strength.
    - i. Strength of the drug.
  - e. “Use by” date.
    - i. Date by which medication should be used; not expiration date of medication or expiration date of prescription.
    - ii. Format as: “Use by: MM/DD/YY.”
- B. Important Information for Patients – Must appear on the label but should not supersede Critical Information for Patients.
- a. Pharmacy name.
    - i. Name of the dispensing pharmacy. Boards of pharmacy should recognize that some pharmacies “do business as” a name other than the corporate name.
  - b. Pharmacy telephone number.

Report of the Task Force on Uniform Prescription Labeling Requirements

- i. Phone number of the dispensing pharmacy. Recognizing that a central fill pharmacy may be involved in the filling process, boards of pharmacy should not require more than one telephone number on the label.
- c. Prescriber name.
  - i. Name of the prescriber.
  - ii. Format – “Prescriber: [prescriber name].”
- d. “Fill date.”
  - i. Date the prescription is dispensed, which will change with each subsequent refill. Format – “Date filled: MM/DD/YY.”
  - ii. The “fill date” and “use by” date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.
  - iii. The term “fill date” should be defined in the *Model Act*.
- e. Prescription number.
  - i. Identifies the number of the pharmacy record under which the prescription information is recorded.
- f. Drug quantity.
  - i. Quantity of drug dispensed.
  - ii. Format – “Qty: [number].”
- g. Number of refills.
  - i. Number of remaining refills.
  - ii. Format – “Refills: [number remaining]” or “No refills,” using whole numbers only and managing partial fills through the pharmacy recordkeeping system.
- h. Product description.
  - i. Written or graphic description of medication dosage form.
- i. Auxiliary information.
  - i. Auxiliary labels – information should be evidence based, standardized, and demonstrated to compliment the prescription label.

Examples of compliant labels include the following:

Pharmacy Name: Phone:	Date Filled: MM/DD/YY Rx No.:	Cautions:
<b>Purpose:</b> <b>Patient Q. Name</b> Prescriber: <b>Take 1 tablet in the morning and 2 tablets at bedtime.</b> <b>Drug Name and Strength</b> Generic for:	Qty: Refills:	Description:
Use by: MM/DD/YY		

**Report of the Task Force on Uniform Prescription Labeling Requirements**

Pharmacy Name: Phone: Patient Q. Name Rx No.: Date Filled: MM/DD/YY Prescriber: Drug Name and Strength Generic for: Qty:                      Refills: Use by: MM/DD/YY	Purpose:  Take 1 tablet in the morning and 2 tablets at bedtime.  Cautions:  Description:
--	---

**Recommendation 3:**

The task force recommends that NABP work with federal and state agencies and pharmacy stakeholders to advocate for and ultimately achieve changes in state or federal laws and regulations and industry standards to support a patient-centered label.

**Background:**

The task force recognized that Recommendation 2 represents a significant change in the philosophy of what defines a prescription label and the purpose of the prescription label. In some situations, this recommendation will be contrary to existing federal and state laws and regulations and industry standards. The *Model Act* cannot and is not intended to contravene state and/or federal laws or regulations. The task force understands this and supports NABP working with relevant agencies and organizations to allow the use of a patient-centered label.

**Recommendation 4:**

The task force recommends that the NABP Executive Committee approve amendments to the *Model Act* to note that the following additional data elements may appear on the prescription label:

- Bar codes
- Pharmacy address
- Pharmacy store number

**Background:**

The task force wanted to give states the option to allow pharmacies to include these elements on the label if they felt they were necessary.

**Recommendation 5:**

The task force recommends that NABP work with relevant organizations, including the American Medical Association, the Federation of State Medical Boards, and the Centers for Medicare and Medicaid Services (CMS), to require that medication indications be included on all prescriptions including but not limited to written and electronic prescription drug orders.

**Background:**

Task force members agreed that this item of information is vital for appropriate medication counseling. It was felt that this was a good time to approach CMS about the possibility of requiring prescribers to include such information in order to be reimbursed for their services.

# Attachment 3

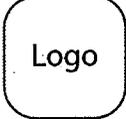
## *Samples of Patient-Centered Prescription Labels*

<p><b>Patient S. Name</b></p> <p><b>Ursodiol 300MG Capsule</b> <b>Generic for Actigall</b></p> <p><b>Take capsule twice a day</b> <b>with food</b></p>	<div data-bbox="894 513 979 610" style="border: 1px solid black; padding: 2px; display: inline-block;">  </div> <p>Pharmacy Name</p> <p>1625 N. Market Blvd Sacramento, CA 95834 (555) 555-5555 Rx #: 1234567 Refill: 0 Prescriber: Dr. Smith</p>
<p>White, Oblong Capsule Expires: MM/DD/YY      Quantity: 25</p>	

<p><b>Patient S. Name</b></p> <p><b>Ursodiol 300MG Capsule</b> <b>Generic for Actigall</b></p> <p><b>Take capsule twice a day with food</b></p>	<div data-bbox="933 1300 1018 1397" style="border: 1px solid black; padding: 2px; display: inline-block;">  </div> <p>Pharmacy Name</p> <p>1625 N. Market Blvd Sacramento, CA 95834 (555) 555-5555</p> <p>Rx #: 1234567 Refill: 0 Prescriber: Dr. Smith</p>
<p>White, Oblong Capsule Expires: MM/DD/YY      Quantity: 25</p>	

	Pharmacy Name	Rx #: 1234567	Refills: 3
	1625 N. Market Blvd Sacramento, CA 95834 (555) 555-5555	Qty: 100 Expires: MM/DD/YY	
Patient S. Name	Take one capsule twice a day with food		
Condition:			
<b>Ursodiol 300MG</b>			
Generic for: Actigall			
Physical Description: White, Oblong Capsule			
Prescriber: Dr. Jonathan D. Smith			

	<b>Pharmacy Name</b>	(555) 555-5555
	1625 N. Market Blvd Sacramento, CA 95834	
<b>Ursodiol 300MG Capsule</b> Generic for Actigall Take capsule twice a day with food		
Patient S. Name		
Condition		
Rx #: 1234567    Refills: 0		
Qty: 50		
Expiration Date: MM/DD/YY		
Prescribed by:		

	Pharmacy Name 1625 N. Market Blvd Sacramento, CA 95834 (555) 555-5555	Rx #: 5555555 Qty: 100 Expires: MM/DD/YY Refills: 3
	Patient S. Name Condition: <b>Fluoxetine 20MG</b> Generic for: Prozac Physical Description: Capsule  Prescriber: Dr. Smith	Take one capsule by mouth one time daily

Pharmacy Name	(555) 555-5555
1625 N. Market Blvd, Sacramento, CA 95834	
Patient S. Name	Use intramuscularly
EPIPEN 0.15 MG	lateral thigh as
2-PAK AUTO-IDEY	needed for severe
Rx #: 1234567	allergic reaction
Qty: 2	
Expires: MM/DD/YY	
Refills: 1 before MM/DD/YY	
Prescriber: Prescriber S. Name	

Rx #: 7777777 Qty: 480ML Expires: MM/DD/YY Refills: 2	Pharmacy Name 1625 N. Market Blvd Sacramento, CA 95834 (555) 555-5555	
Patient S. Name Condition: <b>Promethazine/Codeine Syrup</b> Physical Description: Clear, Purple-Red, Peach-Mint, Syrup  Prescriber: Dr. Smith	Take one table spoon three times a day as needed for cough	

# Attachment 4

## *Standardized Directions for Use on Labels*

## PROTOTYPE DOSAGE INSTRUCTIONS FOR PHARMACY TRASCRIPTION

ENGLISH	SPANISH
Take 1 tablet at bedtime	Tome 1 pastilla en la noche
Take 2 tablets at bedtime	Tome 2 pastillas en la noche
Take 3 tablets at bedtime	Tome 3 pastillas en la noche
Take 1 tablet in the morning	Tome 1 pastilla en la mañana
Take 2 tablets in the morning	Tome 2 pastillas en la mañana
Take 3 tablets in the morning	Tome 3 pastillas en la mañana
Take 1 tablet in the morning, and Take 1 tablet at bedtime	Tome 1 pastilla en la mañana, y 1 pastilla en la noche
Take 2 tablets in the morning, and Take 2 tablets at bedtime	Tome 2 pastillas en la mañana, y 2 pastillas en la noche
Take 3 tablets in the morning, and Take 3 tablets at bedtime	Tome 3 pastillas en la mañana, y 3 pastillas en la noche
Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening	Tome 1 pastilla en la mañana, 1 pastilla en el mediodía, y 1 pastilla en la noche
Take 2 tablets in the morning, 2 tablets at noon, and 2 tablets in the evening	Tome 2 pastillas en la mañana, 2 pastillas en el mediodía, y 2 pastillas en la noche
Take 3 tablets in the morning, 3 tablets at noon, and 3 tablets in the evening	Tome 3 pastillas en la mañana, 3 pastillas en el mediodía, y 3 pastillas en la noche
Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening, and 1 tablet at bedtime	Tome 1 pastilla en la mañana, 1 pastilla en el mediodía, 1 pastilla en la tarde, y 1 pastilla en la noche
Take 2 tablets in the morning, 2 tablets at noon, 2 tablets in the evening, and 2 tablets at bedtime	Tome 2 pastillas en la mañana, 2 pastillas en el mediodía, 2 pastillas en la tarde, y 2 pastillas en la noche
Take 3 tablets in the morning, 3 tablets at noon, 3 tablets in the evening, and 3 tablets at bedtime	Tome 3 pastillas en la mañana, 3 pastillas en el mediodía, 3 pastillas en la tarde, y 3 pastillas en la noche
Take 1 tablet as needed for pain. You should not take more than X tablets in one	Tome 1 pastilla cuando la necesita Ud. para el dolor.

day.	Ud. no debería tomar más de X pastillas en un día.
Take 2 tablets as needed for pain. You should not take more than X tablets in one day.	Tome 2 pastillas cuando las necesita Ud. para el dolor. Ud. no debería tomar más de X pastillas en un día.



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

**Date: July 9, 2009**

**To: Communication and Public Education Committee**

**Subject: Development of New Consumer Brochures**

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For the past year, the focus of work around the board's Communication and Public Education Committee has primarily centered on the standardization of the prescription label.

However, board staff continues to work on the development of new consumer education materials, as well as updates to existing materials. Several are currently undergoing review internally and will be provided to the committee at a future committee meeting. Below is a list of the materials.

Materials for Applicants

U-Track Application Sheets for Pharmacist Applicants

1. Graduate of a Foreign School of Pharmacy
2. U.S. School of Pharmacy Graduate and NOT Licensed in another U.S. State
3. U.S. School of Pharmacy Graduate and Currently Licensed in another U.S. State

Materials for Consumers

1. Preventing Falls
2. Put the chill on myths about colds and flu
3. An Aspirin a day? maybe...check it out
4. Bringing prescription drugs into the U.S. from foreign countries
5. What you should know before buying prescription drugs on the Internet
6. Counterfeit drugs
7. Drug Discount Programs



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ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 9, 2009**

**To: Communication and Public Education Committee**

**Subject: Update and Discussion on Consumer Fact Sheets**

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Several years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The intent was to offer students the opportunity to work with the board on meaningful projects promoting consumer education, while the board would benefit from the production of the materials. Initially the project was initiated with UCSF.

At the October 2007 Board Meeting, the board accepted the committee's recommendation to invigorate this program by offering other schools of pharmacy the opportunity to have their students develop one-page fact sheets on various topics, and then have the developed fact sheets reviewed by an expert. Representatives from other California pharmacy schools were very interested in this project for their students. At that time, the board directed staff to proceed with the committee's recommendation for development of a template for future fact sheets, and work with the schools of pharmacy to initiate this intern project.

Executive Officer Herold contacted each of the schools of pharmacy. Western and USC have confirmed their participation. Board staff is finalizing a template to provide to each school that participates as well as a list of potential subjects.

During a previous committee meeting, Hank Hough, a previous board member, suggested that the board sponsor a contest to recognize the efforts of the interns. Parameters for this have not yet been established; however the committee may wish to do at a future meeting.



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ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 9, 2009**

**To: Communication and Public Education Committee**

**Subject: Notice of Consumers Poster Translations**

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AB 2583 (Nation, Chapter 487, Statutes of 2006): required the board to update its Notice to Consumer to include additional information about a patient's right to obtain lawfully prescribed medicine from a pharmacy. The Notice to Consumer requirement is in 16 CCR 1707.2(g). As such, to implement the provisions in AB 2538, the board sought a regulation change.

In November 2007, the Office of Administrative Law approved amendments to 16 CCR section 1707.2(g), creating additional requirements for a Notice to Consumers poster that present information about a patient's right to obtain lawfully prescribed medicine from a pharmacy. This required notice must be posted in a pharmacy, or alternatively, printed on the back of customer receipts. The board prints these posters so they have a consistent look from pharmacy to pharmacy.

The final design has been selected and the board will print and mail the posters to all California pharmacies in July 2008. More recently the board was able to have these notices translated and printed in four additional languages: Spanish, Chinese, Vietnamese, and Tagalog. The translated versions can be downloaded from the board's Web site, <http://www.pharmacy.ca.gov/publications/publications.shtml>



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ARNOLD SCHWARZENEGGER, GOVERNOR

**Date: July 9, 2009**

**To: Communication and Public Education Committee**

**Subject: Update on The Script**

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Work on the July 2009 issue of *The Script* is completed and the text is undergoing legal review. The issue will focus issues involving pharmacy law and the Integrate Waste Management Board's Model Guidelines for drug-take back programs.

Future publication of *The Script* may be done electronically, rather than in print. Publication expenses of the February issue of *The Script*, was

Production and mailing expenses to 8,700 copies to pharmacies, wholesalers and for limited distribution in the future (lobby of the board office, association meetings):

Print	\$9,060
Mass Mail Process.	326
Presort Postage	<u>3,080</u>
	\$12,386

Simply mailing notices to licensees is costly time-wise and in dollars. In January, 2009, the board sent a one-page letter to all California-licensed pharmacists (34,000+), advising them of requirements of SJR 19 (Ridley-Thomas) related to torture and treatment of licensess. This mailing cost \$11,452.

Printing	\$2,228
Mass mailing proces.	837
Postage	<u>8,387</u>
	\$11,452



**California State Board of Pharmacy**

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

**Date: July 9, 2009**

**To: Communication and Public Education Committee**

**Subject: Update on Public and Licensee Outreach**

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Public and licensee outreach activities performed during the fourth quarter of Fiscal Year 08/09 include:

- April 1, 2009 - Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a California Society of Health-System Pharmacists Town hall meeting at Loma Linda for 80 pharmacists.
- April 2, 2009 - Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a CSHP Town hall meeting at UOP for 60 pharmacists.
- April 17, 2009 - Assistant Executive Officer Sodergren provided a legislative update to the CSHP Board of Director's meeting.
- April 22 - 24, 2009 - Board Member Swart participated in an accreditation review by the national Accreditation Council for Pharmacy Education of the California North State School of Pharmacy.
- April 28, 2009 - Executive Officer Herold presented information about California's e-pedigree requirements via web cast at the RFID Journal Annual Technology Conference in Florida.
- April 28, 2009 - Executive Officer Herold presented via web cast to the Center for Business Intelligence Annual Drug Security Conference in Philadelphia information about California's e-Pedigree requirements.
- April 29, 2009 - Executive Officer Herold presented information about the board's six sponsored bills at CSHP Legislation Day.
- May 11, 2009 - Licensing Manager Debbie Anderson provided a presentation to students at Loma Linda University on becoming licensed as pharmacists in California.
- May 14, 2009 - Board Member Swart provided a presentation to students at the University of the Pacific on pharmacy law and the board.
- May 21, 2009 - Board President Schell made a presentation to UC San Diego students regarding intern hour requirements.



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

**Date: July 23, 2008**

**To: Communication and Public Education Committee**

**Subject: Update of the Committee's Strategic Plan for 2009/10**

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## **Attachment B-9**

In July 2006, the board finalized its strategic plan for 2006-2011. However, each year the board revises its plan to keep it current.

At this meeting, the committee will have the opportunity to revise its strategic plan, if warranted.

During the July Board Meeting, the board will review any modifications to the strategic plan recommended by each committee for development of the 2008-09 strategic plan (completing the annual updating process).

Update of the Committee's Strategic Plan for 2009/10

## COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goal 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1	Develop a minimum of 10 communication venues to the public by June 30, 2011.
Measure:	Number of communication venues developed to the public
Tasks:	<ol style="list-style-type: none"> <li>1. Assess the effectiveness of the board's educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired.</li> <li>2. Restructure the board's Web site to make it more user friendly.</li> <li>3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics.</li> <li>4. Continue collaboration with UCSF's Center for Consumer Self Care for pharmacist interns to develop consumer fact sheets on health topics.</li> <li>5. Develop a Notice to Consumers to comply with requirements of SB 2583 (Nation) on patients' rights to secure legitimately prescribed medication from pharmacies.</li> <li>6. Evaluate the practice of pill splitting as a consumer protection issue.</li> <li>7. Evaluate the SCR 49 Medication Errors Report for implementation.</li> <li>8. Develop patient-centered standardized prescription container labels by 2011.</li> <li>9. Address and promote licensee and public education on minimizing prescription errors.</li> </ol>
Objective 4.2	Develop 10 communication venues to licensees by June 30, 2011.
Measure:	Number of communication venues developed to licensees
Tasks:	<ol style="list-style-type: none"> <li>1. Publish <i>The Script</i> two times annually.</li> <li>2. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California.</li> <li>3. Maintain important and timely licensee information on Web site.</li> </ol>
Objective 4.3	Participate in 12 forums, conferences and public education events annually
Measure:	Number of forums participated
Tasks:	<ol style="list-style-type: none"> <li>1. Participate in forums, conferences and educational fairs.</li> </ol>



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

**Date: July 23, 2008**

**To: Communication and Public Education Committee**

**Subject: Fourth Quarter Report on Committee Goals for 2008/09**

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**Attachment B-10**

Following in **Attachment B-10** are the fourth quarter's strategic goal updates for 2008/09.

# COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goal 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1	Develop a minimum of 10 communication venues to the public by June 30, 2011.
Measure:	Number of communication venues developed to the public.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="365 457 1485 745"> <p>1. <b>Assess the effectiveness of the board’s educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired.</b>  <i>2006-2007: Staff conducts assessment of the board's consumer outreach written materials. Material is identified for revision and update, future development, or evaluation for continued need.</i>  <i>2007-2008: Board publishes new board brochure and complaint brochure, and redesigns several board brochures into new single-page, format.</i></p> </li> <li data-bbox="365 745 1485 1123"> <p>2. <b>Restructure the board’s website to make it more user friendly.</b>  <i>2006-2007: Website modified to contain lists of disciplinary actions finalized each quarter and permit online access to public documents regarding board disciplinary actions taken against a licensee.  Links added to obtain various information regarding medication safety, and drug interactions, and information from FDA regarding Medications and Medical Devices.  Work Initiated on new website design to meet new state design standards.</i>  <i>2007-2008: New website design completed in November 2007.  Web page created consolidating all information on e-pedigree into one place.</i></p> </li> <li data-bbox="365 1123 1485 1344"> <p>3. <b>Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics.</b>  <i>2006-2007: Committee continues collaboration with the partnership whose fall campaign is screening for prostate and breast cancer. Plans underway to work to promote generic drugs in the future.  No additional meetings scheduled after January 2007.</i></p> </li> <li data-bbox="365 1344 1485 1890"> <p>4. <b>Continue collaboration with schools of pharmacy for pharmacist interns to develop consumer fact sheets on health topics.</b>  <i>2006-2007: Nine previously developed fact sheets are sent to a translation service to develop Spanish, Chinese, and Vietnamese versions of these materials. Four new fact sheets developed and undergoing review by the board.</i>  <i>2007-2008: The committee determines that the board will expand the project beyond the Center for Consumer Self Care to include students from other Schools of Pharmacy.  Meanwhile discussion with UCSF lead to request for funding to continue project.  Meanwhile board seeks to establish intern projects with other schools of pharmacy.</i>  <i>1st Qtr. 08/09: Letter to Deans of California's pharmacy schools mailed.</i>  <i>1st Qtr. 09/10: Staff prepare to initiate program using intern coordinators at school of pharmacy campuses in California.</i></p> </li> </ol>

	<p>5. <b>Develop a Notice to Consumers to comply with requirements of AB 2583 (Nation, Chapter 487, Statutes of 2006) on patients' rights to secure legitimately prescribed medication from pharmacies.</b></p> <p><i>2006-2007: Governor signs AB 2583. Committee advances draft regulation text for comment at the October Board Meeting. Board votes to create a second Notice to Consumers poster vs. adding additional language to current poster. Committee refines language to be advanced to the board. Board reviews, modifies, and sets for regulation notice the proposed language for a second Notice to Consumers poster.</i></p> <p><i>2007-2008: New "Notice to Consumers" approved by board and later by the Office of Administrative Law. New design and layout for two new Notice to Consumer posters are selected.</i></p> <p><i>1st Qtr. 08/09: New posters are mailed to California pharmacies.</i></p> <p><i>2nd Qtr. 08/09: Posters are translated into several languages and made available on the board's website.</i></p> <p>6. <b>Evaluate the practice of pill splitting as a consumer protection issue.</b></p> <p><i>2006-2007: Board holds discussion of pill splitting issues during January and April 2007 Board Meetings.</i></p> <p><i>2007-2008: <u>The Script</u> newsletter contains an article for pharmacists on pill splitting and a Fact Sheet for consumers is completed.</i></p> <p>7. <b>Evaluate the SCR 49 Medication Errors Report for implementation.</b></p> <p><i>2006-2007: Communication and Public Education Committee reviews SCR 49 report and board has presentation of the SCR 49 report.</i></p> <p><i>2007-2008: SB 472 enacted to require the board to standardize container labels into a patient friendly format by 2011.</i></p> <p><i>Feb. 2009: SB 470 introduced to add "purpose" to the prescription container's label.</i></p>
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- 8. Develop patient-centered standardized prescription container labels by 2011 pursuant to SB 472 (Corbett, Chapter 470, Statutes of 2007).**
- Oct. 2007: Board president appoints members to subcommittee.*
- Jan 2008: Board readies plans for six public hearings statewide during 2008*
- April 2008: First meeting in Fremont on April 12. Approximately 40 people attend.*
- Apr.-Jul. 08: Board attends health fairs and interviews patients for information on how to improve prescription labels. Survey available on board's website. 123 surveys completed.*
- July 2008: Board Inspector Bayley and Associate Analysts Durst and Abbe staff a resource table at the Lotus Festival in Los Angeles and interview attendees about their prescription labels as part of the board's initiative to implement a patient-centered prescription label.*
- Aug. 2008: Associate Analysts Durst and Abbe and Assistant Executive Officer Sodergren staff the department's booth at the State Fair and distribute brochures, respond to public questions and elicit suggestions to improve the labeling on prescription labels.*
- Oct. 2008: Board Member Powers provides information and conducted labeling surveys of those attending CARA's annual meeting. Publications Coordinator Abbe attends Celebrando Nuestra Salud to conduct labeling surveys of those in attendance.*
- Nov. 2008: Board sponsors public forum on health literacy and designing patient-centered labels. National experts provide information.*
- Dec. 2008: Board Executive Officer participates on National Association of Boards of Pharmacy task force to develop national standards for patient-centered labels. Board and CPhA develop joint survey for administration via listeners of radio stations on patient medication labels.*
- Jan. 2009: Over 600 consumer surveys submitted; SB 472 Subcommittee meets to begin developing regulations. Radio surveys add 1,800 additional survey responses. Subcommittee holds afternoon meeting in San Diego.*
- March 2009: Evening meeting held on SB 472 task force draws a few more public attendees. Ongoing surveys from consumers continues.*
- July 2009: Draft regulation language discussed by board.*
- 9. Address and promote licensee and public education on minimizing prescription errors.**
- July 2008: Forum on medication errors held as part of board meeting. Michael Cohen, Institute of Safe Medical Practices, John Keats, California Patient Action Coalition, and Lorian deMartini, California Department of Public Health, talk about activities of their organizations to prevent errors. Board Inspector Orlandella represented the board on a panel to a group of seniors in Roseville, California.*
- Jan. 2009: Board publishes medication errors segment in its newsletter, The Script, describing several medication errors investigated by the board.*
- June 2009: Enforcement Committee hears presentation on board investigations of medication errors during 2008/2009.*

Objective 4.2	Develop 10 communication venues to licensees by June 30, 2011.
Measure:	Number of communication venues developed to licensees.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1524 436"> <p>1. Publish <i>The Script</i> two times annually.</p> <p><i>July 2008:</i> <i>The Script</i> published, placed online and mailed to pharmacies and wholesalers.</p> <p><i>April 2009:</i> "February" issue of <i>The Script</i> published, placed online and mailed to pharmacies and wholesalers.</p> <p><i>July 2009:</i> "July" issue of <i>The Script</i> written and undergoing review.</p> </li> <li data-bbox="370 436 1524 1239"> <p>2. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California.</p> <p><i>2006-2007:</i> The board's members, supervising inspector and executive officer provide 22 CE and licensee educational seminars during the year.</p> <p><i>2007-2008:</i> The board's members, supervising inspector and executive officer provide at least 10 CE and licensee educational seminars during the year.</p> <p><i>1st Qtr 08/09:</i> Board Member Goldenberg provides information about pharmacy law to medical staff at the Jewish Home Hospital in Los Angeles. President Schell speaks on requirements regarding conscience provisions in California law at Loma Linda University.</p> <p><i>2nd Qtr 08/09:</i> Executive Officer Herold speaks to the CSHP's Board of Directors about the board's heparin inspections. Executive Officer Herold speaks to CSHP's Seminar on Board legislative and regulation activities. Assistant Executive Officer Sodergren and Supervising Inspector Ratcliff staff an informational booth at CSHP's Seminar. Executive Officer Herold speaks to CSHP's Seminar on the heparin inspections conducted with the California Department of Public Health in California Hospitals. Executive Officer Herold speaks to CSHP's Seminar on California's e-pedigree requirements.</p> </li> </ol>

**3rd Qtr 08/09:** Executive Officer Herold and Board President Schell provide three presentations at the California Pharmacists Association's Outlook on the Board of Pharmacy, major issues before the board and medication errors. Supervising Inspector Ratcliff provides a presentation about pharmacy law to 70 students at Loma Linda's School of Pharmacy. President Schell provides a presentation on Board of Pharmacy issues to the San Diego CPhA meeting. Supervising Inspector Ratcliff presents information on "How to Survive a Board Inspection" to 80 pharmacists at a Vietnamese Pharmacist Association. Board President Schell provides a presentation to UCSF School of Pharmacy on ethics and integrity in pharmacy. Board President Schell provides a presentation to UCSF School of Pharmacy on ethics and integrity in pharmacy. Executive Officer Herold and President Schell present a 1.5 hour CE lecture on the Board of Pharmacy at that CPhA's annual meeting. Supervising Inspector Ratcliff and Assistant Executive Officer Sodergren staff a booth at the CPhA's annual meeting answering pharmacy law and licensing questions. Executive Officer Herold and President Schell discuss the role of a regulatory agency in investigating and preventing medication errors as CPhA's annual meeting. Executive Officer Herold provides presentation to UCSF and UCSD students in a first year pharmacy school law class. President Schell provides a presentation to students at the USC School of Pharmacy.

**4th Qtr 08/09:** Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a California Society of Health-System Pharmacists Town hall meeting at Loma Linda for 80 pharmacists. Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a CSHP Town hall meeting at UOP for 60 pharmacists.

**3. Maintain important and timely licensee information on website.**

**2006-2007:** Added 50-year pharmacist recognition pages as a special feature. Updated license totals. Added enforcement actions for effective dates between April 1 and June 30, 2005. Changed definitions on license lookup to clarify license status. Sent out more than 50 subscriber alert notifications to the board's e-mail notification list. Unveiled new website of the board, and created new web links. Revised and added new fax and contact information to speed communication with appropriate enforcement and licensing staff. Added frequently asked questions on emerging contraception. Updated the board's online lawbook. Created a page dedicated to drug alerts and recalls.

	<p><b>2007-2008:</b> <i>Added information about NAPLEX being suspended. Added information about Heat Preparedness. Added information about pill-splitting. Sent out more than 55 subscriber alert notifications to the board's e-mail notification list. Website reflecting the New State Redesign launched in November 2007. Sent out three disaster response subscriber alerts regarding the Southern California wildfires to the board's e-mail notification list. Created a page dedicated to e-pedigree information and laws. Updated the 2008 lawbook. Added two sets of comments submitted to the FDA in support of a unique identifier and on promising technologies for prescription drug identification, validation, track and trace or authentication to e-pedigree page. Added survey of patients for prescription container labels. Added page for subscription to board mailing list.</i></p> <p><b>1st Qtr 08/09:</b> <i>Updated information regarding release of exam results. Added enforcement actions for the effective dates between July 1 and September 30, 2008. Added two recall notifications to FDA recall page. Posted board and committee meeting agendas and materials. Sent out 24 subscriber alert notifications to the board's email notification list.</i></p> <p><b>2nd Qtr 08/09:</b> <i>Updated online renewal forms for individual licenses. Created information on CURES page. Created a survey page for public opinion on how to improve prescription labels (SB 472) in English and Spanish. Added three recall notifications to FDA recall page. Posted board and committee meeting agendas and materials. Sent out 20 subscriber alert notifications to the board's email notification list.</i></p> <p><b>3rd Qtr 08/09:</b> <i>Began process of making all PDFs on board's website accessible for the visually impaired. Added four recall notifications to FDA recall page. Posted board and committee meeting agendas and materials. Sent out 27 subscriber alert notifications to the board's email notification list. Posted latest edition of <u>The Script</u>.</i></p> <p><b>4th Qtr 08/09:</b> <i>Continued making all PDFs on board's website accessible for the visually impaired. Updated lawbook to 2009 edition. Added four recall notifications to FDA recall page. Posted board and committee meeting agendas and materials. Sent out 26 subscriber alert notifications to the board's email notification list.</i></p> <p><b>4. Jan 2009:</b> <b>Board mails letter pursuant to SJR 19 (Ridley-Thomas, Statutes of 2008) regarding prohibition of healing arts licensees not to engage in torture.</b></p>
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Objective 4.3	Participate in 12 forums, conferences and public education events annually.
Measure:	Number of forums participated.
Tasks:	<p><b>1. Participate in forums, conferences and educational fairs.</b></p> <p><b>July 2008:</b> Board Member Goldenberg provides information about pharmacy law to medical staff at the Jewish Home Hospital. Board Inspector Orlandella represents the board to a group of seniors and provided general information and responded to questions in Roseville, CA Executive Officer Herold provides a presentation to a group of 150 individuals and agencies regarding California law and drug take back programs in communities. Board staff attend the Lotus Festival in Bakersfield, CA and distribute consumer brochures and interview attendees about their prescription labels as part of the board's initiative to implement a patient-centered prescription label.</p> <p><b>Aug. 2008:</b> Associate Analysts Durst and Abbe and Assistant Executive Officer Sodergren staff the department's booth at the State Fair and distribute brochures, respond to public questions and elicit suggestions to improve the labeling on prescription labels. Executive Officer Herold provides a presentation at a conference sponsored by the California Integrated Waste Management Board on the board's concerns with drug take back programs and sharps container returns.</p> <p><b>Sept. 2008:</b> Executive Officer Herold provides a presentation to AstraZeniga's government relations staff on SB 1307. Executive Officer Herold provides a presentation at the Generic Pharmaceutical Association's annual meeting on SB 1307. Executive Officer Herold participates in a web cast on California's pedigree requirements and SB 1307 (Ridley-Thomas) hosted by software provider SAP. Board President Schell and Executive Officer Herold make a presentation at a national meeting held in Sacramento regarding California's pharmacy law and the requirements barring needles and syringes being inappropriately discarded in landfills and other locations.</p> <p><b>Oct. 2008:</b> Executive Officer Herold speaks at CSHP Seminar providing three major presentations: 2008 Laws and Regulations, the 2008 Heparin Inspections, and an e-pedigree update.</p> <p><b>Nov. 2008:</b> Executive Officer Herold and Assistant Executive Officer Sodergren attend Synergy 2009, an event sponsored by the California Pharmacists Association.</p> <p><b>Nov. 2008:</b> Board hosts two major forums on public policy. The board's forum on e-prescribing brings in national and state experts in a session designed for healing arts boards. The forum on designing patient-centered labels has national experts and health literacy advocates.</p> <p><b>Dec. 2008:</b> Board President Schell serves on a National Association of Boards of Pharmacy Task Force on the take back of drugs from the public.</p>

**3rd Qtr 08/09:** Executive Officer Herold and Board President Schell provide three presentations at the California Pharmacists Association's Outlook on the Board of Pharmacy, major issues before the board and medication errors. President Schell provides a presentation on prescription drug safety at the California Science Center in Los Angeles.

Supervising Inspector Ratcliff provides a presentation about pharmacy law to 70 students at Loma Linda's School of Pharmacy.

President Schell provides a presentation on Board of Pharmacy issues to the San Diego CPhA meeting.

Supervising Inspector Ratcliff presents information on "How to Survive a Board Inspection" to 80 pharmacists at a Vietnamese Pharmacist Association.

Board President Schell provides a presentation to UCSF School of Pharmacy on ethics and integrity in pharmacy.

Executive Officer Herold provides an update on board activities to the California Society of Health-Systems Pharmacists Board of Directors.

Board President Schell provides a presentation to undergraduate students of UCSD on career paths in pharmacy.

Supervising Inspector Ratcliff provides a presentation to the South Bay Pharmacists Association on "Surviving an Inspection."

Executive Officer Herold presents at the Pharmacy Foundation of California's Award Ceremony honoring a patient education advocate.

Executive Officer Herold and President Schell present a 1.5 hour CE lecture on the Board of Pharmacy at that CPhA's annual meeting.

Executive Officer Herold serves as one of three judges for patient education videos produced by students as part of the CPhA's annual meeting. The winning videos will be promoted by the board.

Supervising Inspector Ratcliff and Assistant Executive Officer Sodergren staff a booth at the CPhA's annual meeting answering pharmacy law and licensing questions.

Executive Officer Herold and President Schell discuss the role of a regulatory agency in investigating and preventing medication errors as CPhA's annual meeting.

Executive Officer Herold provides presentation to UCSF and UCSD students in a first year pharmacy school law class.

President Schell provides a presentation to students at the USC School of Pharmacy.

President Schell spoke at an Eagle Scout ceremony in Sacramento.

**4th Qtr 08/09:** *Executive Officer Herold attends annual National Association of Boards of Pharmacy meeting.*

*Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a California Society of Health-System Pharmacists Town hall meeting at Loma Linda for 80 pharmacists.*

*Executive Officer Herold presented information about the Board of Pharmacy and ongoing projects at a CSHP Town hall meeting at UOP for 60 pharmacists.*

*Assistant Executive Officer Sodergren provided a legislative update to the CSHP Board of Director's meeting.*

*Board Member Swart participated in an accreditation review by the national Accreditation Council for Pharmacy Education of the California North State School of Pharmacy.*

*Executive Officer Herold presented information about California's e-pedigree requirements via web cast at the RFID Journal Annual Technology Conference in Florida.*

*Executive Officer Herold presented via web cast to the Center for Business Intelligence Annual Drug Security Conference in Philadelphia information about California's e-Pedigree requirements.*

*Executive Officer Herold presented information about the board's six sponsored bills at CSHP Legislation Day.*

*Licensing Manager Debbie Anderson provided a presentation to students at Loma Linda University on becoming licensed as pharmacist s in California.*

*Board Member Swart provided a presentation to students at the University of the Pacific on pharmacy law and the board.*

*Board President Schell made a presentation to UC San Diego students regarding intern hour requirements.*