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**State of Connecticut**  
**HOUSE OF REPRESENTATIVES**  
STATE CAPITOL  
HARTFORD, CONNECTICUT 06106-1591

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ADVANCEMENT COMMITTEE  
INSURANCE & REAL ESTATE COMMITTEE  
PUBLIC HEALTH COMMITTEE

Testimony By:  
Rep. James Maroney  
February 21, 2013

HB: 5418 "An Act Concerning Prescription Drug Labels"

Good afternoon,

Representative Baram, Senator Doyle, Senator Witkos, Representative Carter, and members of the General Law committee. Thank you for the opportunity to testify in support of **HB 5418 – An Act Concerning Prescription Drug Labels**.

According to the Institute of Medicine - National Academy of Sciences, at least 1.5 million people every year are affected by medication errors. According to Families USA, nearly forty percent of medications are taken incorrectly by Medicare patients. This statistic is even more troubling when coupled with the fact that ninety percent of Medicare patients take at least daily medications to treat chronic conditions. According to a study led by Dr. Leora Horwitz, a practitioner at Yale New Haven Hospital, eighty-one percent of patients experienced either a provider error in their discharge medication, or had no understanding of at least one intended medication change. Further, here are some other troubling findings:

- Up to one-half of all medications are taken incorrectly or mixed with other medications that cause dangerous reactions that can lead to injury and death.
- Approximately 46 percent of American adults cannot understand the label on their prescription medications.

The intent of HB 5418 is to improve the labeling of prescription medication by making directions easier to understand. This can be accomplished by providing more specific instructions for use, improving font size and type, and adding additional language options. Together, these changes will help citizens from all walks of life have a better understanding of how to properly take their prescribed medication.

I understand there may be hesitation in passing legislation that could result in an increased cost or regulation to the prescription drug industry, but there are too many people in our society that are currently suffering from medication errors. After speaking with my local pharmacist, I learned that most of these recommendations are already part of their prescription drug software.

There is a similar version of HB 5418 that was passed in the State of California in 2007. Included in my testimony today are copies of the California bill (SB 472), analysis of the California bill, and the proposed amendments to the original bill.

Overall, when a patient properly takes their prescribed medication, they are more likely to have a quicker recovery. This will prevent the risk of a relapse of the original condition, and could prevent additional hospitalization or treatment, saving the patient and State of Connecticut in health care costs. Ultimately, the goal of this bill is to increase consumer protection and increase the health, safety, and well-being of consumers.

Thank you for the opportunity to testify today. I am willing to answer any questions.

Sincerely,

Representative James Maroney  
119<sup>th</sup> Assembly District

## Board of Pharmacy

### Initial Statement of Reasons

Hearing Date: January 20, 2010

Subject Matter of Proposed Regulation: Patient-Centered Prescription Labels

Sections Affected: Add 16 Cal.Code Reg. §1707.5

#### Specific Purpose of the Proposed Changes:

Existing law sets forth the requirements for a prescription drug container label for any drug dispensed to a patient in California (Business and Professions Code section 4076). However, existing law does not describe with specificity what elements are necessary to make the label "patient-centered," as required by Business and Professions Code section 4076.5. Proposed regulation at Section 1707.5 specifies *how* prescription drug information is to be placed on the prescription drug container label, and clarifies what interpretive services are required to be provided by pharmacies in compliance with Section 4076.5 of the Business and Professions Code.

As mandated by Business and Professions Code section 4076.5 (The California Patient Medication Safety Act enacted by SB 472, Stats. 2007, ch. 470) and to make specific the prescription drug container label requirements found in Business and Professions Code section 4076, the Board of Pharmacy has proposed to add Section 1707.5 to Title 16 of the California Code of Regulations. This proposal would establish the requirements for a standardized, patient-centered prescription drug container label. This regulation would, among other things, mandate the format of all prescription drug container labels for prescription drugs dispensed in California, including: font type, font size, placement, wording, and grouping of information. It would require pharmacists, when applicable, to use standardized words and phrases, as specified, to describe directions for use of the drug on the drug container label.

This regulation would also require the California State Board of Pharmacy (Board) to publish on its Web site by October 2011 translations of certain directions for use, as specified, into at least five (5) languages other than English to facilitate the use of these translations by pharmacies. The Board would also be required, beginning in October 2010, to collect and publish on its Web site examples of labels conforming to the requirements of this proposed regulation.

In addition, this regulation would require a pharmacy, upon request by a patient with limited English proficiency, to provide oral translation of the prescription drug container label's information.

Under this proposal, the Board would be required to re-evaluate the requirements of this regulation by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5

### Factual Basis/Rationale

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 4076 specifies information that is required to be placed on a prescription drug container label dispensed to a patient in California.

Business and Professions Code section 4076.5 requires the board to promulgate regulations on or before January 1, 2011, that require a standardized, patient-centered prescription drug container label for all prescription drugs dispensed to patients in California. It also specifies what factors the Board of Pharmacy must consider in establishing such a label. Those factors include:

- Medical literacy research
- Improved directions for use
- Improved font types and sizes
- Placement of information that is patient-centered
- Needs of patients with limited English proficiency
- Needs of seniors
- Technology requirements for implementation

### Background

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

Additionally, Senator Ellen Corbett authored SB 472, resulting in the enactment of the California Patient Medication Safety Act (Chapter 470, Statutes of 2007). Therein, the Legislature stated the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling—which can increase consumer protection and improve the health, safety and well-being of consumers. Additionally, the Legislature affirmed the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems in order to identify and encourage the adoption of structural safeguards related to prescription drug container labels. To further these objectives, the Legislature authorized the Board per SB 472 (now Business and Professions Code section 4076.5) to adopt regulations to implement standardized, “patient-centered” prescription drug container labels in California.

To facilitate development of this regulation proposal, the President of the Board appointed a SB 472 Label Subcommittee to conduct public forums and to develop recommendations to implement the provisions of SB 472 to establish a patient-centered prescription drug label. Public forums, separate from regularly-scheduled board meetings, were held throughout the state. At these public forums, at other outreach events, through its Web site, and at other board and committee meetings, the board sought public input and feedback on what elements of a prescription drug container label were important to them and how that label could be improved. The board developed and made available to the public a prescription label survey 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 Web site 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. Survey results were provided to the board at SB 472 Subcommittee public forums and at public board meetings.

At public forums and at board and committee meetings, the board considered testimony and information provided on medical literacy research, improved directions for use, improved font types and sizes, the placement of information that is patient-centered, the needs of patients with limited English proficiency, the needs of senior citizens, and technology requirements necessary to implement the standards developed. The minutes of these meetings, as well as the documents listed in the "Underlying Data" section, reflect the information received and considered. Based upon the foregoing information received and considered by the Board, the Board developed this proposed language to implement the requirements of Business and Professions Code section 4076.5.

In exercising its authority over the practice of pharmacy in the state of California, the board believes that this proposed regulation is necessary to implement Section 4076.5. By providing a uniform, standardized format for prescription drug container labels and requiring pharmacies to provide oral language translations to patients with limited English proficiency, the Board believes that this proposed regulation will aid in the reduction of medication errors associated with the delivery of prescription drugs dispensed to patients in California. (Subsections (a), (d) of proposed Section 1707.5.)

This regulation is also necessary to assist pharmacies with implementation of the new patient-centered drug container label standards contained in the proposed regulations. Proposed subsections (b) and (c) would require the Board to publish on its Web site by October 2011 translations of certain directions for use, as specified, into at least five (5) languages other than English. The Board would also be required, beginning in October 2010, to collect and publish on its Web site examples of labels conforming to the requirements of this proposed regulation. The board intends to address this in two ways. First, the board is working with health care advocates to

translate the standard directions for use phrases identified in subparagraph (a)(4) and have those available on the board's Web site by October 2011. Second, subdivision (d) contains language requiring a pharmacy, upon request of the patient, to provide an oral language interpretation of the prescription drug label information specified in subdivision (a)(1) for non-English speaking patients. The board received testimony from chain and retail pharmacy industry representatives that this service is already provided to their non-English speaking patients and that providing this service would not impose any further economic impact.

To ensure continuing consideration and analysis of the effectiveness of this proposal in light of the factors contained in Section 4076.5 (e.g., new developments in technology), this regulation is necessary to mandate that the board will re-evaluate the requirements of the regulation by December 2013.

#### Underlying Data

1. Senate Concurrent Resolution No. 49—Relative to Medication Errors. Resolution Chapter 123, Filed with Secretary of State September 2005.
2. SCR 49 Final Report on Medication Errors
3. SCR 49, Senate Health Committee Analysis (for bill version 6/15/05, hearing date 6/22/05)
4. Senate Bill 470 (Corbett)—Chapter 472, Statutes of 2007
5. Meeting Materials and Minutes from
  - a. Senate Bill 472 Medication Label Subcommittee Public Forums

April 12, 2008	January 27, 2009	
November 20, 2008	March 12, 2009	
  - b. Communication and Public Education Committee Meetings

June 27, 2007	January 8, 2008	July 23, 2008
	April 12, 2008	October 2, 2008
  - c. Legislation and Regulations Committee Meetings

April 2007	July 10, 2008	
July 5, 2007	October 29, 2008	
  - d. Board of Pharmacy Meetings

August 19, 2009		
October 21-22, 2009		
6. Hernandez, Lyla M., Rapporteur. Roundtable on Health Literacy. "Standardizing Medication Labels: Confusing Patients Less, Workshop Summary." ISBN: 0-309-11530-2

7. Testimony from Doreena Wong, National Health Law Program, November 20, 2008; and Issue Brief: Language Services in Pharmacies: What is Required?
8. Board of Pharmacy Prescription Container Label Survey; survey responses; and Fact sheet: Do you understand the directions on your Rx medicine label?
9. Improving Prescription Drug Container Labeling the United States, A Health Literacy and Medication Safety Initiative. A White Paper commissioned by the American College of Physicians Foundation, October 12, 2007.
10. *Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review*, The Annals of Pharmacotherapy, 2007 May, Volume 41
11. Shrank, William H., MSHS, MD; Agnew-Blais, Jessica, BA; Choudhry, Niteesh K., MD PhD; Wolf, Michael S., PhD, MPH; Kesselheim, Aaron S., MD, JD; Avorn, Jerry, MD; Shekelle, Paul, MD PhD. *The Variability and Quality of Medication Container Labels*. ARCH INTERN MED/VOL 167 (No. 16), September 10, 2007.
12. 2009-2010 Chain Industry Pharmacy Profile, National Association of Chain Drug Stores

#### Business Impact

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the following facts or evidence/documents/testimony and also applies to pharmacies outside of California that provide prescription drug products to California patients.

Consistent with the requirements of Senate Bill 853 (Escutia, Chapter 713 Statutes of 2003), the Department of Managed Health Care and the Department of Insurance have established regulations that require oral language interpretation services for their patients with limited English proficiency at all points of care. To facilitate clients with these requirements, many pharmacies already provide such interpretive services to California patients. The board heard testimony in October 2009 from the California Retailers Association as well as pharmacy chain representatives who indicated that the interpretive language services provided to patients with limited English proficiency are already provided to their pharmacy patients.

One industry member testified at the October 2009 board meeting that they may incur one-time costs to configure the labeling of that pharmacy's prescription drug label – resulting in a one-time approximate cost of \$1,000.

To determine the number of small businesses that may be affected by this proposed regulation, the board utilized data from the National Association of Chain Drug Stores (NACDS) 2009-2010 Chain Pharmacy Industry Profile (2008 data), which reports that in 2008 California had 4,828 chain drug, supermarket, mass merchant and independent drug store locations. Of that number, NACDS

considers 1,670 (or approximately 35%) to be independent pharmacies. The board also utilized its own licensee data that shows that as of December 2008 the board issued licenses to 6,149 pharmacies. (This number does not include those licenses issued to correctional facilities, hospitals or licensed clinics – these are pharmacies that rarely dispense prescription drug medications to outpatients.) Utilizing the NACDS profile data, if 35% of California’s pharmacies are considered independent pharmacies, this would represent that – using actual licensee data – California would have approximately 2,150 independent pharmacies.

Additionally, as of December 2008, California issued licenses to 359 non-resident pharmacies – those located outside the state that ship, mail, or deliver, in any manner, controlled substances, dangerous drugs, or dangerous devices into California. The board does not maintain separate statistics to show if these licensees are independent, community, or chain drug stores; however, the board does not believe these licensees are small businesses.

Likewise, the board included in the proposed regulation, the board’s requirement to re-evaluate the requirements of the regulation by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

To address the needs of patients with limited English proficiency and who require oral language interpretation of prescription drug label information, subdivision (d) of the proposed regulation contains language requiring a pharmacy, upon request of the patient, to provide an oral language interpretation of the prescription drug label information specified in subdivision (a)(1). The board received testimony from chain and retail pharmacy industry representatives that this service is already provided to patients with limited English proficiency and that a regulation requiring a pharmacy to provide this service would not impose any further economic impact. Additionally, and as required in subdivision (b) of the proposed regulation, the board will post on its Web site the translation of the standard directions for use phrases (subdivision (a)(4)) in five non-English languages. The board will work with health care advocates to develop these translations at no cost to the agency.

#### Specific Technologies or Equipment

While this regulation does not mandate the use of specific technologies or equipment, pharmacies may need to modify how their prescription container labels are printed so as to be in compliance with the font type, font size and placement of information on a prescription drug container label for prescription drugs dispensed to a patient in California.

#### Consideration of Alternatives

The Board of Pharmacy is mandated to promulgate regulations to specify a standardized, patient-centered prescription drug container label by January 1, 2011. Therefore, failing to adopt regulations is not a legally viable alternative.

The board considered information and testimony received over a period of approximately 18 months and believes that no alternative it considered would be either more effective than or as effective as and less burdensome on affected private persons than this proposed regulation.

No reasonable alternative to amending the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons than the proposed regulation.

BILL NUMBER: SB 472        CHAPTERED  
BILL TEXT

CHAPTER 470  
FILED WITH SECRETARY OF STATE    OCTOBER 11, 2007  
APPROVED BY GOVERNOR    OCTOBER 11, 2007  
PASSED THE SENATE    SEPTEMBER 6, 2007  
PASSED THE ASSEMBLY    SEPTEMBER 5, 2007  
AMENDED IN ASSEMBLY    AUGUST 30, 2007  
AMENDED IN ASSEMBLY    JUNE 20, 2007  
AMENDED IN SENATE    MAY 21, 2007  
AMENDED IN SENATE    APRIL 30, 2007  
AMENDED IN SENATE    APRIL 16, 2007  
AMENDED IN SENATE    APRIL 9, 2007

INTRODUCED BY    Senator Corbett  
(Coauthors: Assembly Members Berg, Karnette, and Ma)

FEBRUARY 21, 2007

An act to add Section 4076.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 472, Corbett. Prescription drugs: labeling requirements.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy in the Department of Consumer Affairs. Existing law prohibits a pharmacist from dispensing a prescription, except in a container that meets certain labeling requirements.

This bill would require the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The bill would require the board to hold special public meetings statewide in order to seek information from certain groups, and would require the board to consider specified factors in developing the label requirements. The bill would require the board to report to the Legislature on or before January 1, 2010, on its progress at the time of the report, and to report to the Legislature on or before January 1, 2013, on the status of implementation of the requirements.

Because a knowing violation of the Pharmacy Law constitutes a crime, and because the above-described provisions would impose additional duties under that law, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. This act shall be known and may be cited as the California Patient Medication Safety Act.

SEC. 2. The Legislature hereby finds and declares all of the following:

(a) Health care costs and spending in California are rising dramatically and are expected to continue to increase.

(b) In California, prescription drug spending totaled over \$188 billion in 2004, a \$14 billion dollar per year spending increase from 1984.

(c) Prescription drug cost continues to be among the most significant cost factors in California's overall spending on health care.

(d) According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people every year.

(e) Up to one-half of all medications are taken incorrectly or mixed with other medications that cause dangerous reactions that can lead to injury and death.

(f) Approximately 46 percent of American adults cannot understand the label on their prescription medications.

(g) Ninety percent of Medicare patients take medications for chronic conditions and nearly one-half of them take five or more different medications.

(h) Nearly six out of 10 adults in the United States have taken prescription medications incorrectly.

(i) The people of California recognize the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling, which can increase consumer protection and improve the health, safety, and well-being of consumers.

(j) The Legislature affirms the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems in order to identify and encourage the adoption of structural safeguards related to prescription drug container labels.

(k) It is the intent of the Legislature to adopt a standardized prescription drug label that will be designed by the California State Board of Pharmacy for use on any prescription drug dispensed to a patient in California.

SEC. 3. Section 4076.5 is added to the Business and Professions Code, to read:

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.

(2) Improved directions for use.

(3) Improved font types and sizes.

(4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.

(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

## BILL ANALYSIS

SB 472  
Page 1

Date of Hearing: June 26, 2007

ASSEMBLY COMMITTEE ON HEALTH  
Mervyn Dymally, Chair  
SB 472 (Corbett) - As Amended: June 20, 2007

SENATE VOTE : 27-10

SUBJECT : Prescription drugs: labeling requirements.

SUMMARY : Requires the Board of Pharmacy to promulgate regulations that require a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. Specifically, this bill :

- 1) Requires the Board of Pharmacy to do all of the following:
- a) Promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California;
  - b) Hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties;
  - c) Consider all of the following factors when developing the requirements for prescription drug labels:
    - i) Medical literacy research that points to increased understandability of labels;
    - ii) Improved directions for use;
    - iii) Improved font types and sizes;
    - iv) Placement of information that is patient-centered;
    - v) The needs of those patients with limited English proficiency;
    - vi) The needs of seniors; and,
    - vii) Technology requirements necessary to implement the standards;
  - d) Report to the Legislature by January 1, 2010, on its progress under this bill; and,
  - e) Report to the Legislature by January 1, 2013, the status

SB 472  
Page 2

of implementation of the prescription drug label requirements adopted pursuant to this bill.

- 2) Makes various findings related to the cost and use of prescription drugs and the need to reduce medication-related errors.

EXISTING LAW

- 1) Establishes the Pharmacy Law which provides for the licensing, regulation and enforcement of the practice of pharmacy by the Board of Pharmacy. Makes it a misdemeanor to violate the Pharmacy Law.
- 2) Requires dispensed prescription drugs to be correctly labeled with all of the following:
  - a) The trade name of the drug or the generic name and the name of the manufacturer;
  - b) The directions for the use of the drug;
  - c) The name of the patient;
  - d) The name of the prescriber;
  - e) The date of issue;
  - f) The name and address of the pharmacy, and the prescription number;
  - g) The strength of the drug;
  - h) The quantity of the drug or drugs dispensed;
  - i) The expiration date of the effectiveness of the drug;
  - j) The condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription; and,
  - aa) The physical description of the drug, including its color, shape, and any identification code that appears on the tablets or capsules, except as specified.

FISCAL EFFECT : According to the Senate Appropriations Committee pursuant to Senate Rule 28.8, negligible state costs.

COMMENTS :

1) PURPOSE OF THIS BILL . According to the author, this bill is necessary to make prescription drug labels easy to understand. The author cites a number of reports as evidence of the need for this bill. According to the Institute of Medicine, medication errors are among the most common medical errors, harming at least 1.5 million people annually. An article in

SB 472  
Page 3

the Journal of the American Medical Association states that 46% of adults cannot understand the information on the label of their pill bottles. A 2006 Annals of Internal Medicine study found that although 70.7% of patients with low literacy could correctly repeat dosing instructions, only 34.7% could demonstrate the correct number of pills to be taken daily. Families USA reports that 40% of medications are taken incorrectly by Medicare patients. According to the 2005 U.S. Census, more than one in five Californians speak English "less than very well." Separate studies show that limited English proficient patients have a harder time understanding the information on their prescription drug labels and have lower levels of adhering to their medication regimens. For all these reasons, the author believes that standardized prescription drug labels would facilitate patient understanding of the information contained on these labels.

2) BACKGROUND . In March 2007, the Medication Errors Panel (Panel) established pursuant to SCR 49 (Speier), Resolution Chapter 123, Statutes 2005, published its report, Prescription for Improving Patient Safety: Addressing Medication Errors.

The report listed six general goals to reduce medication errors. Under each goal were recommendations (twelve in all) and methods to accomplish each recommendation. The goal relevant to the subject matter of this bill is: "Improve prescriber-pharmacist and pharmacist-consumer communications to enhance understanding of the intended use of prescribed medication." To accomplish this goal, the panel made the following relevant recommendation:

Require that the intended use of the medication be included on all prescriptions and require that the intended use of medication be included on medication label/labeling unless disapproved by the prescriber or the patient. (The Panel's method to accomplish this is for the California boards of pharmacy and medicine to pursue necessary statutory and regulatory changes.)

3) PRESCRIPTION LABELS AND LABELING. The Panel report states that "the information that consumers need to know about their medication is often complex and may include unfamiliar language or concepts. Expecting a consumer to retain all the pertinent knowledge from a brief verbal encounter may not be reasonable in many instances." The report continues:

For this reason, it is important that consumers also

SB 472  
Page 4

receive written information regarding their prescription. Often-times however, even this information can be forgotten and lost, and in those instances, consumers may be left with nothing more than the prescription packaging and label to guide them. Testimony provided to the Panel identified many limitations related to the prescription label as an effective communication tool. These included the limited size of a prescription label (approximately 2 x 3 inches) which, due to established pharmacy systems, processes, and drug container variability would be functionally and financially difficult for the pharmacy industry to change. Further complicating matters is the fact that there is already a significant amount of information required by California law to be printed on the label. The most recent label requirement went into effect on January 1, 2006 and was created to help consumers identify erroneously filled prescriptions by mandating that pharmacies include the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. . . . While this requirement is obviously directed at reducing errors, one might question the utility of some of the other [state-mandated] label requirements . . . Given the limited space available, are all of these elements the most valuable pieces of information for the patient?

4) CONSUMERS AT HIGH RISK FOR MEDICATION ERRORS . Although the Panel did not come to consensus on the most important subset of consumers that are at "high risk" for medication errors, it did acknowledge that there are a variety of factors which may increase an individual's risk for experiencing a medication error. These include: a) low health literacy; b) limited English proficiency; c) cultural incongruence with healthcare providers; d) physical, cognitive and/or other impairments that make understanding and/or complying with medication instructions difficult; e) age at either end of the age spectrum (the variability of a medication's response, metabolism and dose increases in children and seniors); f) multiple medications; g) multiple prescribers; h) non-prescription medication use (including herbals, dietary supplements, alcohol and tobacco); and, i) medication procurement from more than one pharmacy including mail-order. The Panel did state that these factors must be taken into consideration in the development of any consumer education efforts.

SB 472  
Page 5

5) SUPPORT . Proponents state that prescription medications are an essential part of health care and contribute to increasing both quality and life expectancy of patients, but despite their importance, many Californians face challenges understanding and complying with their medication regimen. All too often, medical errors have dire consequences. In fact, proponents argue, medication errors are a leading cause for hospitalizations in the United States. Proponents further suggest that national trends are moving toward improving the readability of prescription labels. They state that Target Pharmacy has created the ClearRX system to reduce medication errors, and Walgreen's Pharmacy produces labels in more than 10 languages, indicating that standardization and translation are realistic goals for California.

6) OPPOSITION . The California Retailers Association and Rite Aid write, in opposition to a prior version of this bill, that they oppose the creation of a new panel separate from the Board of Pharmacy and language that directs the panel's priorities. The California Alliance for Consumer Protection, also writing in opposition to a prior version of this bill, argues against its adoption because it does not cover Rx Cannabis products or prescription drug samples. It is unclear if the current version of this bill addresses opponents' concerns.

7) RELATED LEGISLATION . AB 1276 (Karnette), which would have required prescribers of medications to ask the patient, whether to indicate the intended purpose of the prescription on the prescription's label, failed passage in the Assembly Business and Professions Committee.

8) DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Business and Professions Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

Latino Coalition for a Healthy California (sponsor)  
Gray Panthers California (sponsor)  
Senior Action Network (sponsor)  
California State Board of Pharmacy

SB 472  
Page 6

AIDS Healthcare Foundation  
American Federation of State, County and Municipal Employees  
Applied Research Center  
Asian Pacific American Legal Center of Southern California  
California Alliance for Retired Americans  
California Association of Public Authorities for In- Supportive Services  
California Medical Association  
Latino Health Alliance  
Mexican American Legal Defense and Education Fund  
Pharmacist's Planning Service, Inc.  
Southern California HIV Advocacy Coalition

Opposition

California Alliance for Consumer Protection  
California Retailers Association  
Rite Aid

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097