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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
SENATE BILL 472 MEDICATION LABEL SUBCOMMITTEE
MINUTES

DATE: March 12, 2009

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

BOARD MEMBERS PRESENT:
Kenneth Schell, PharmD, Committee Chair
Robert Swart, PharmD
Susan L. Ravnan, PharmD
William Powers, Public Member

BOARD MEMBERS NOT PRESENT: Shirley Wheat, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Carolyn Klein, Legislation and Regulations Manager
Karen Abbe, Public and Licensee Education Analyst
Tessa Fraga, Staff Analyst

Call to Order

Chair Schell called the meeting to order at 6:14 p.m.

1. Welcoming Remarks

Dr. Schell provided an overview of the agenda and explained the purpose of the meeting.

2. Review of SB 472 and the Charge to the Board in Developing Patient-Centered Labels

Executive Officer Virginia Herold provided an overview of SB 472 and its requirements.

Ms. Herold indicated that the board must implement the requirements of SB 472 by January 1, 2011. The Board will do this over a phased-in three-year period. During 2008, the board held a series of public meeting throughout California, gathering information and

input from consumers and the health professions for adopting regulations to standardize prescription labels. In 2009, the board will adopt regulations to standardize prescription labels. In 2010, all pharmacies dispensing drugs to California patients must convert their labels to this new format by the 2011 deadline. Ms. Herold provided that the board is currently on schedule.

Ms. Herold provided that regulations will be developed at the April board meeting. She indicated that the board would like to have regulations drafted by July in order for the board to take action by the end of 2009.

Public Comments

Al Hernandez Santana (Latino Coalition for a Healthy California) shared support to the board for its efforts for SB 472. He asked if an opportunity for comments would be available after the regulations have been drafted.

Dr. Schell indicated that there will be an opportunity for further comment.

Mr. Hernandez Santana questioned if the board planned on conducting more public hearings for consumers.

Ms. Herold indicated that the board will continue to conduct consumer surveys at health fairs statewide. She indicated that the public will be provided with a minimum of 45 days for public comment before regulations are adopted. Public comments are reviewed and may be considered for incorporation into the regulation.

Mr. Hernandez Santana urged the board to partner with the Latino Coalition for a Healthy California to ensure that the Latino population is provided an opportunity to provide public input.

Ms. Herold thanked Mr. Hernandez Santana and the Latino Coalition for a Healthy California for their support.

Mr. Schell indicated support and appreciation for the efforts of the Latino Coalition for a Healthy California.

William Powers provided that a Spanish version of the questionnaire is available.

Margy Metzler (Gray Panthers Chapter) offered continued support for the board's efforts towards implementing SB 472.

There was no additional board of public comment.

3. Overview of SB 853 (Escutia, Chapter 713, Statutes of 2003) Health Care Language Assistance

Martin Martinez (California Pan-Ethnic Health Network) provided an overview of SB 853. Passed in 2003, the bill mandates that all California health plans provide language assistance services to their enrollees. The legislation stipulates that all vital documents must be translated into threshold languages and interpretation services made available to enrollees.

Mr. Martinez suggested that the board participate with the implementation of this legislation and the translation of prescription labels.

Dr. Robert Swart expressed concern regarding the difficulty pharmacists may encounter while ensuring the accuracy of labels printed in a foreign language.

Mr. Martinez responded that quality control measures may need to be identified.

Dr. Schell provided that collaborative efforts are required to work towards a solution and to ensure access is not diminished.

There was no additional board of public comment.

4. Review of Consumer Surveys Conducted by the Board of Pharmacy for SB 472

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

Karen Abbe, Public and Licensee Education Analyst, provided that the board conducted one-on-one interviews at 7 consumer outreach events in 2008. The actual survey results from these interviews are available.

Board Discussion:

Mr. Powers expressed concern regarding the sufficiency of the information gathered from the surveys.

Ms. Herold provided that the survey results support the available literature and research on this topic.

Discussion continued regarding sufficient sample size and the accuracy of the survey results.

5. Review of Survey Results from a Joint Survey Developed by the California Pharmacy Foundation and the Board of Pharmacy for SB 472

Presentation to the Board:

Dr. Michael Negrete (Pharmacy Foundation of California):

Dr. Negrete provided an overview of the data results from the joint survey developed by the Pharmacy Foundation of California and the Board of Pharmacy. The survey focused on identifying key attitudes and knowledge of behaviors of California consumers related to prescription drug labels. The multiple choice survey of four questions was conducted via a radio-sponsored survey by Entercom broadcasting.

The four survey questions and their respective top responses are as follows

1. How often do you read the label on your prescription containers? - 42% responded 'Only before I take it the first time.'
2. When you need to obtain information from the label, what do you have the most trouble with? - 44% responded 'finding it.'
3. Which parts of the label are most important to you? - 64% responded 'directions.'
4. What would you change on the prescription label to improve it? – Top responses included bigger print/size, clarity, including the purpose, including side effects/interactions, and the use of "chunking" to present information in identifiable sections.

Dr. Negrete discussed possible limitations of the study including the representation of the sample and the credibility of self-reporting. He provided that directions for use are seen as particularly important and that patients should be encouraged to read their labels more frequently.

Board Discussion:

Dr. Swart discussed the challenges that arise when trying to include information on larger vials. He added that the results from the radio survey support the results from the board's survey.

Mr. Powers provided that he currently receives medications that have the purpose provided on the label.

Assistant Executive Officer Anne Sodergren provided that current law allows for the condition to be included on the prescription if requested by the patient, but not the purpose.

Discussion continued regarding the implications of providing the purpose on the prescription label. A consumer bottle, where the consumer personally wrote the purpose for their medication, was presented as an exhibit.

Public Comments:

Chad Morton suggested that the board consider alternative resources, outside of the label, to convey necessary information to the consumer

Mr. Powers asked Mr. Morton for other suggestions.

Mr. Morton responded that patients need better education. He suggested that the board, along with the pharmaceutical industry and pharmacy profession, think outside of the box.

Ms. Metzler provided that she reads her prescription labels to ensure the information matches the information she received from the doctor.

There was no additional board or public comment.

6. Patient-Focused Elements of Prescription Container Labels (California Business and Professions Code Section 4076)

Ms. Herold provided that the board held a Subcommittee Meeting on January 27, 2009 to evaluate patient-centered elements of prescription labels. Attendees were asked to discuss label requirements and to identify requirements that are the most patient-centered. Requirements identified as being the most patient-centered included patient name, generic name, drug name, drug strength, directions for use, physical description of drug, expiration date, quantity, pharmacy name, pharmacy address, pharmacy phone number, prescription number, refills, and prescriber.

Ms. Herold presented a variety of sample labels emphasizing these requirements. She provided that these labels can be used as a model. Ms. Herold discussed the implications of standardizing label formats, noting that companies are currently utilizing a variety of different shaped containers.

Discussion continued regarding the implications of standardizing label formats.

Public Comments

Dr. Negrete suggested that the board provide companies with approved formats or offer approval of formats that fulfill the patient-centered requirement criteria.

Mr. Morton suggested that the label be used to refer patients to an alternative source of information.

There was no additional board of public comment.

7. Legislative Proposal to Add "Purpose" to Prescription Container Labels

Dr. Schell provided that Senate Bill 470, introduced by Senator Corbett, would revise current law to require the label to include the purpose for which a drug is described if requested by the patient or if the purpose is indicated on the prescription. Dr. Schell added that this bill would result in a conforming change.

Ms. Herold provided that existing law authorizes a prescription to include the condition for which the drug is prescribed if requested by the patient. Ms. Herold discussed concerns regarding challenges to identifying the purpose and possible implications for pharmacy workload. She expressed the importance of adding the purpose to the label at this time and possible impacts for e-prescribing.

Public Comment:

Dr. Negrete offered support for the proposal. He provided that prescribing errors may be eliminated if the prescriber is required to indicate the purpose on the prescription.

There was no additional board or public comment.

8. Public Comment for Items Not on the Agenda

No public comment was received.

The meeting was adjourned at 7:42 p.m.

Pharmacy Foundation of California

Consumer Rx Label Survey

Michael J. Negrete, PharmD
CEO, Pharmacy Foundation of California
www.PharmacyFoundation.org

Survey Objective

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

Methodology

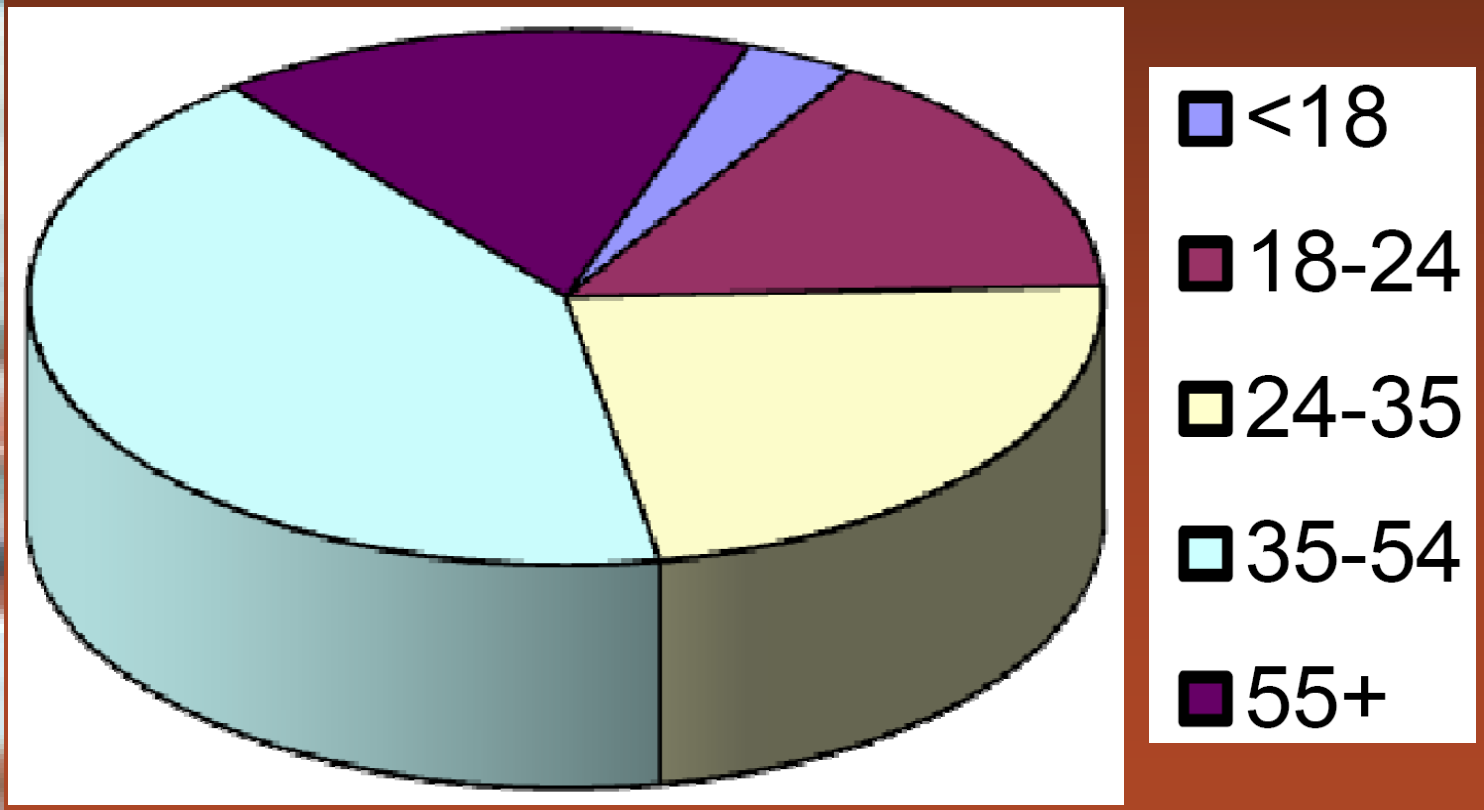
- Online survey distributed by Entercom broadcasting
  - One of the five largest radio broadcasting companies in the United States
  - Nationwide portfolio of 110 stations in 23 markets, including San Francisco, Boston, Seattle, Denver, Portland, Sacramento and Kansas City
- Survey made available during 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?

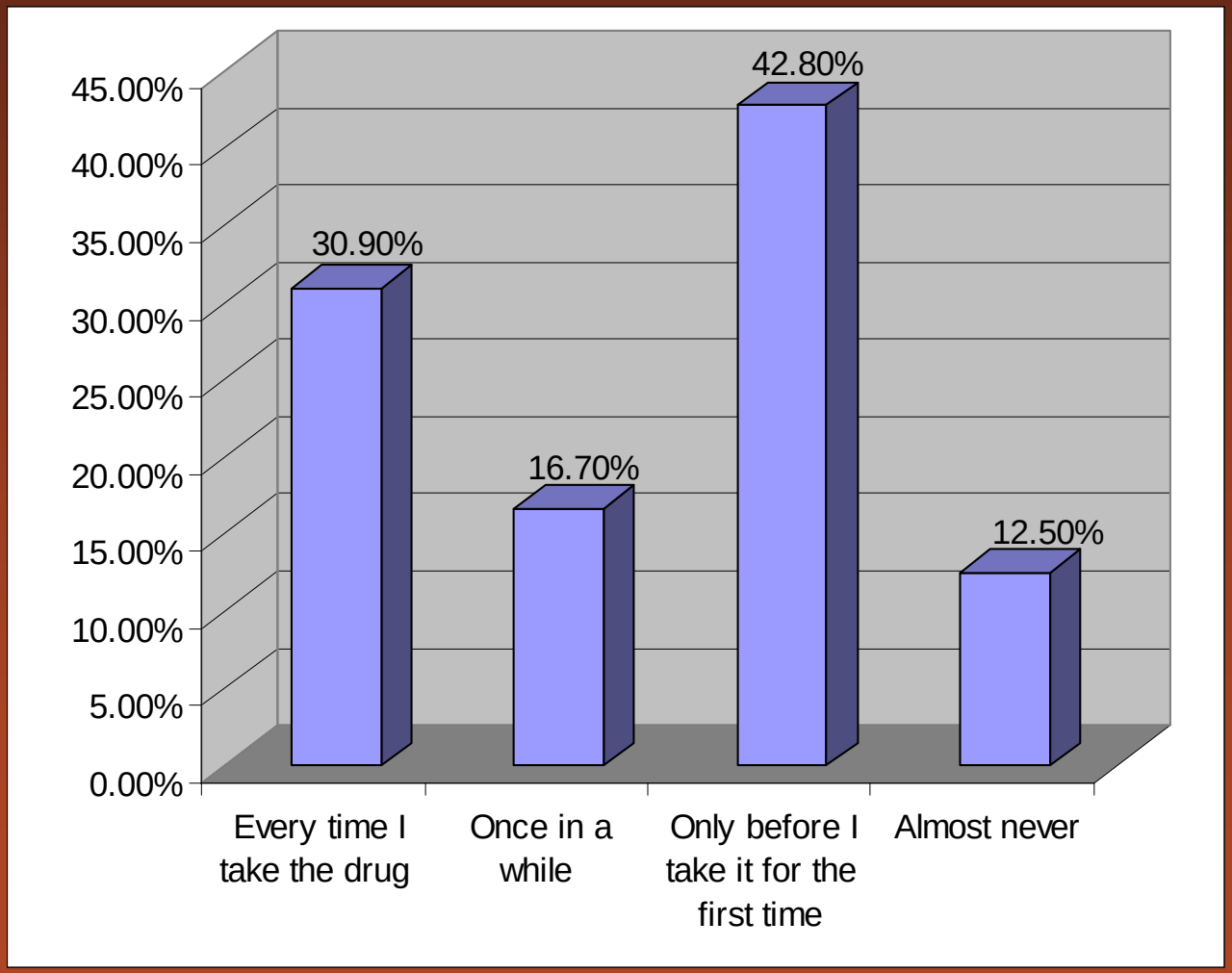
Results

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



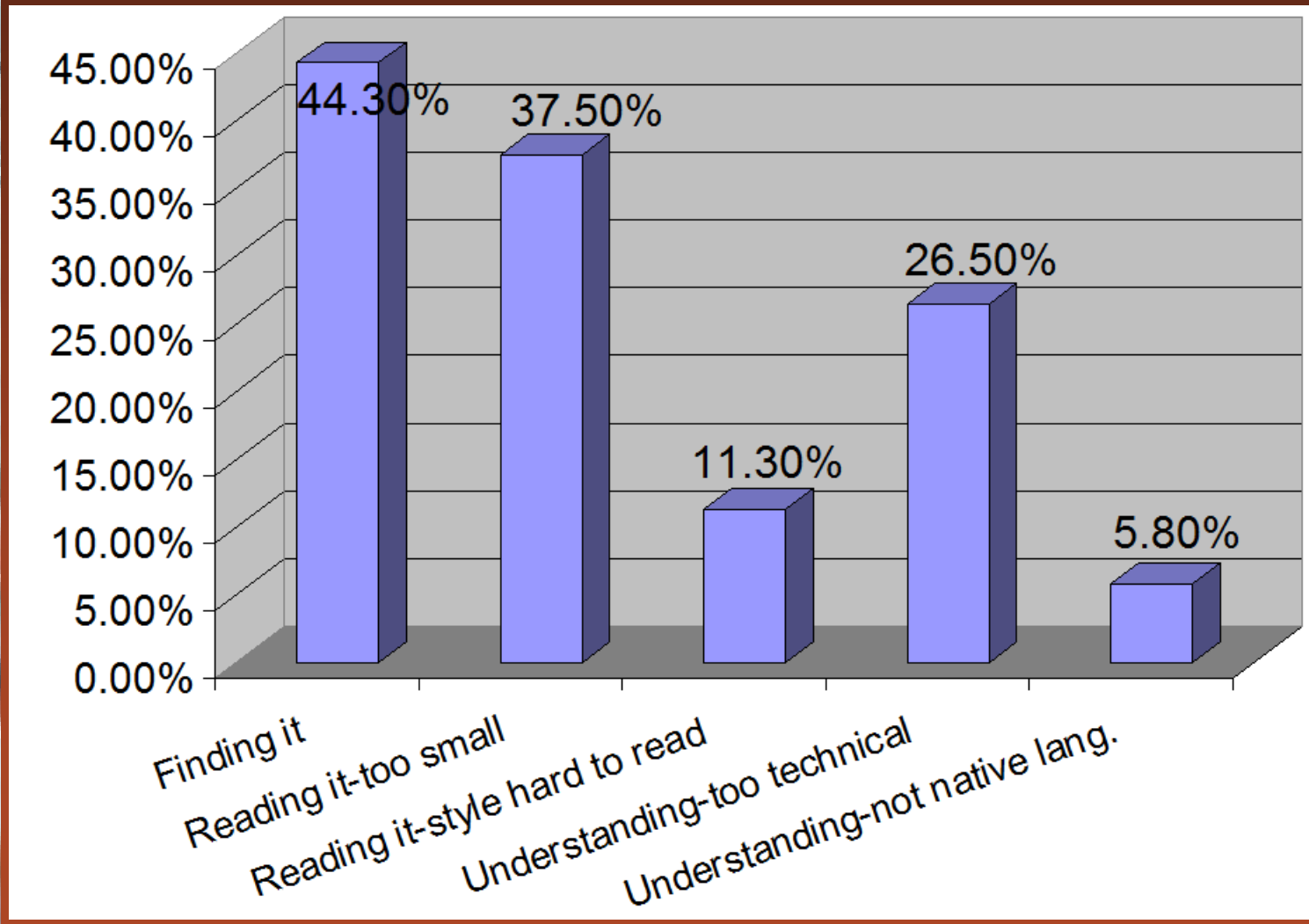
Results

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



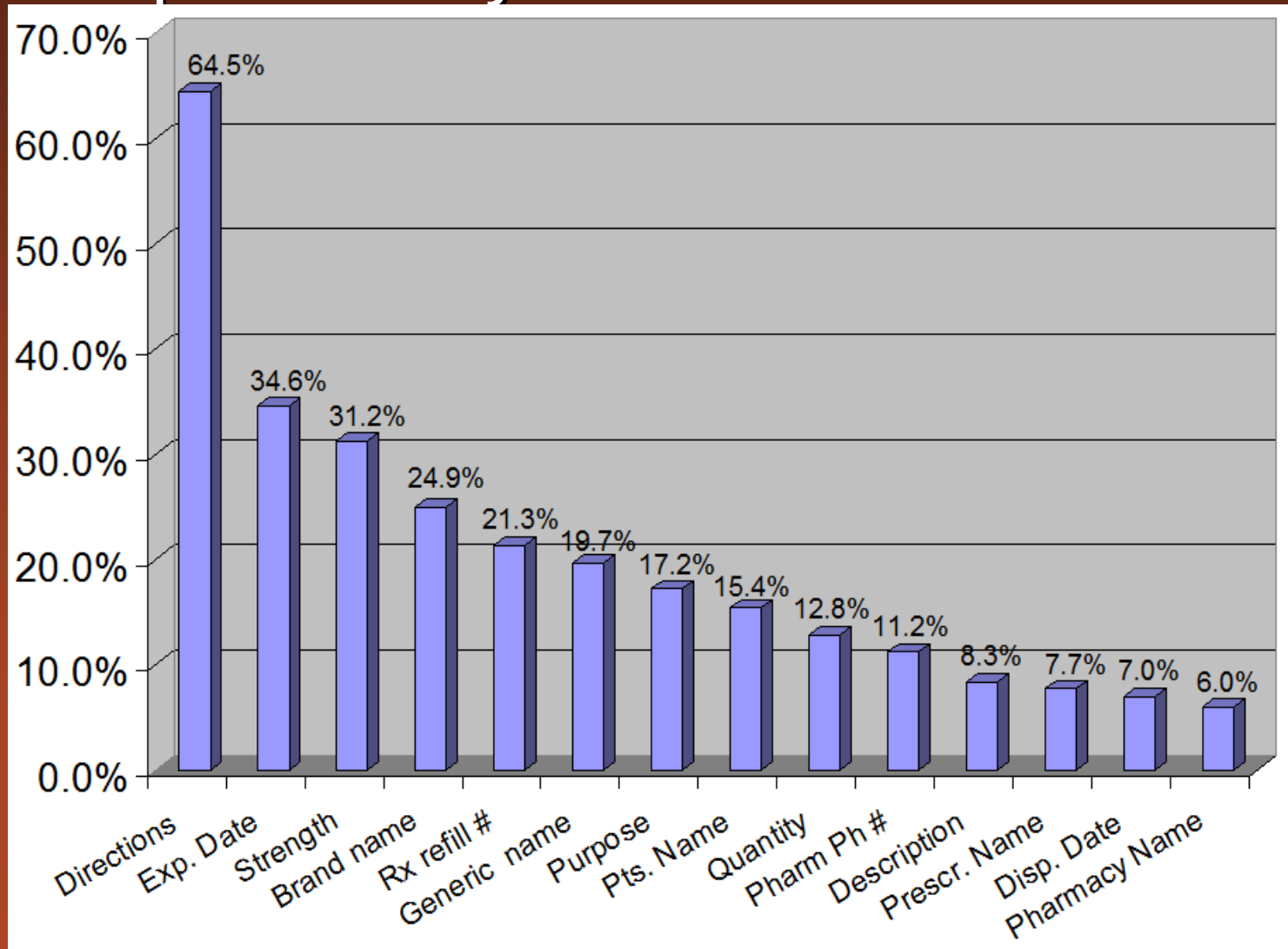
Results

- 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