



# Keynote Address: Progress Report for the Prescription Bottle Labeling Project

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The Prescription Bottle Labeling Project, commissioned by the ACP Foundation, aims to answer a series of critical questions related to prescription bottle labels and their effect on health outcomes in the United States. For example, do labels need to be improved? How are labels currently regulated and is the current system working? Is there a role for government in the labeling process? By exploring these questions, this project will evaluate current prescription bottle labeling in order to determine what changes are needed in order to improve health outcomes.



The project involves an extensive review of medical, marketing, and psychology literature on evidence relating to patient understanding of prescription drug labels including format, content, current regulation, medication errors, and costs of medication errors. The project focuses on the container label<sup>1</sup> as well as the Consumer Medication Information (CMI) leaflet which accompanies most prescriptions. The goal is to consider improvement of container labels and CMI together in order to improve the current system of providing medication information to patients.

“Poor patient understanding of prescription bottle labels results in medication errors and reduced adherence.”

### Is there a need for improvement?

Nearly half of all American adults have difficulty understanding and using health information.<sup>2</sup> This problem is compounded by prescription bottle labels, which are written at a tenth grade reading level or higher and must communicate a great deal of information to the patient on a very small surface area and in very small fonts. Poor patient understanding of prescription bottle labels results in medication

errors and reduced adherence. Patients adhere to only about 50% of prescribed medications. U.S. Pharmacopeia found that about a third of the errors they evaluated were due at least in part to medication labeling problems. In the U.S., non-adherence costs are estimated at \$100 billion per year and are responsible for 11% of hospital admissions and an estimated 125,000 deaths annually.

### What are the research findings so far?

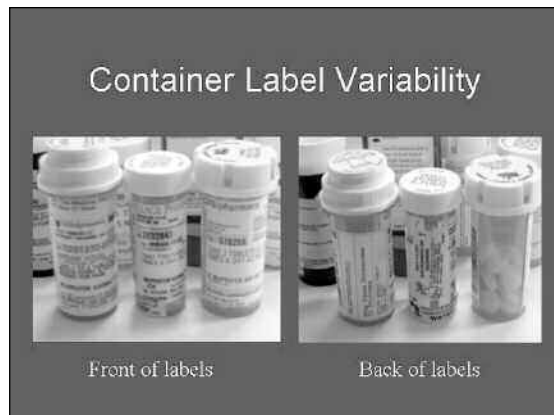
Research indicates that the use of lists, bullets, headers, white space, and a logical organization of concepts in the format of labels and CMI is crucial for optimal patient comprehension. The use of

<sup>1</sup> The container label includes both the sticky label on the bottle and the auxiliary stickers that describe warnings and/or instructions.

<sup>2</sup> Institute of Medicine. 2004. *Health Literacy: A Prescription to End Confusion*



certain typefaces improves readability as does larger print, especially among the elderly. Language written at a 6<sup>th</sup>-8<sup>th</sup>-grade reading level or lower is also important for reading comprehension of the many adults with low health literacy. To maximize the surface area of prescription bottle labels information must be presented in an organized way, but studies do not present clear alternatives to the current system.



With regard to content, patient understanding is optimized when medication instructions are plainly explained, avoiding vague terminology and jargon. Information presented numerically rather than in prose form is easier to understand. In addition, patients benefit from information about side effects and what to do upon onset of side effects. Patients also request better information about the duration of therapy, especially when chronic medications are initiated. Understanding directions, goals of treatment and potential side effects have been shown to improve

adherence, all of which could be influenced by improved labeling.

### **Should the government play a greater role in label regulation?**

Currently, each state's Board of Pharmacy regulates the content of prescription bottle labels. CMI content is determined by several private firms, which compile information about prescription drugs and sell it to pharmacies. The format of both the container label and the CMI is unregulated throughout the U.S. and is determined by individual pharmacies in conjunction with their software vendors. The 1996 Medication Guide Law inserted a certain level of government oversight into the private sector's distribution and quality of CMI. However, a national assessment of CMI in 2000 found that only 20 percent of the CMI that were evaluated met greater than 60 percent of the quality criteria. In 2006, CMI distribution in quality will again be reassessed.

### **Next Steps**

The final report of the ACP Foundation's Prescription Bottle Labeling Project will be released early in 2006. Preliminary research demonstrates that quality of prescription bottle labeling and CMI is a critical issue for policy makers to address. The medical community should play a leadership role in this process and evidence-based strategies should be used.