

# Medication Labeling:

## Can We Confuse Patients Less?



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# ACPF Medication Labeling Project

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- **Recommended by:**
  - Patient Literacy Advisory Board, 2004
  - 2004 National Conference Breakout
- **RFA for evidence based review**
- **Policy Questions:**
  - Do labels need to be improved?
  - What level of evidence is needed?
  - What is the role of various stakeholders?

# Rx Drug Labels: An Evidenced Based Review

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ACPF Expert Panel Meeting 9/6/05

**HARVARD MEDICAL SCHOOL**

*Program for the Analysis  
of Clinical Strategies*



**BRIGHAM AND WOMEN'S HOSPITAL**

*Division of Pharmacoepidemiology  
and Pharmacoeconomics*



William Shrank, MD, MSHS  
Paul Shekelle, MD, PhD  
Jerry Avorn, MD

# Objectives of the Review

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- Define purpose of “labeling”
- Define optimal format and content of labels
- Present rationale for standardized Rx drug labels
- Consider how to implement improved labels





# Evidence and Barriers

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## Research supports...

- View labeling as a system of information
- Poor labeling contributes to poor quality care and an increase in error rates

## Stakeholders' Views

- Overwhelming support for *concept* of improving labels

## Potential opposition to standardization from key stakeholders

- Pharmacies
- Software vendors

# Can We Confuse Patients Less?

An ACPF Medication Labeling Agenda and Call to Action



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# A Summary of the Evidence

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- High prevalence of outpatient medication errors (IOM)
- Patients misunderstand instructions (Davis, et al)
- Current labeling inadequate for patients with limited literacy (Davis, et al)
- Labeling standards limited, with high variability (Shrank, et al)
- Some evidence for improvement (Shrank, et al; Ganley, FDA)

# Current ACPF Objectives

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- Consolidate an understanding of the broad problem of inadequate patient medication information
- Identify a specific course of action to improve drug labeling in the United States





# Prescription Bottle Labeling Project

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- In 2006, ACPF strategic planning group:
  - Examined Prescription Bottle Labeling Project's work to date Discussed level of evidence needed to advance improved labels
  - Envisioned white paper to summarize and catalyze next steps
- Develop components of a prototype model for the prescription bottle label
- Convene stakeholders to provide advice into the strategic plan and the prototype