



ACP Foundation  
Promoting health literacy



NORTHWESTERN  
UNIVERSITY

# Health Literacy & Medication Safety

## Can We Confuse Patients Less?

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Northwestern University

# Acknowledgements



**HeLP**

HEALTH LITERACY AND LEARNING PROGRAM

Feinberg School of Medicine  
Northwestern University

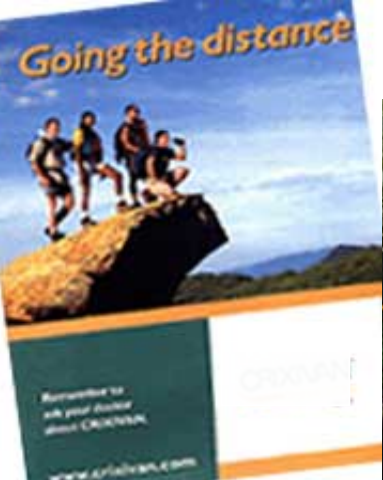
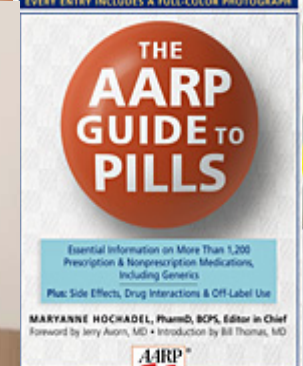
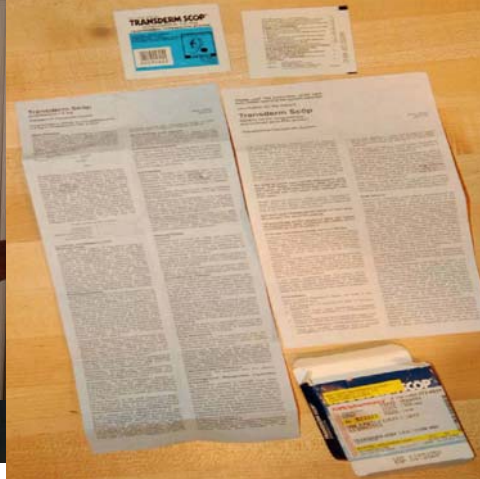
## Partners:

- Ruth Parker, MD (Emory)
- Will Shrank, MD (Harvard)
- Terry Davis, PhD (LSUHSC)

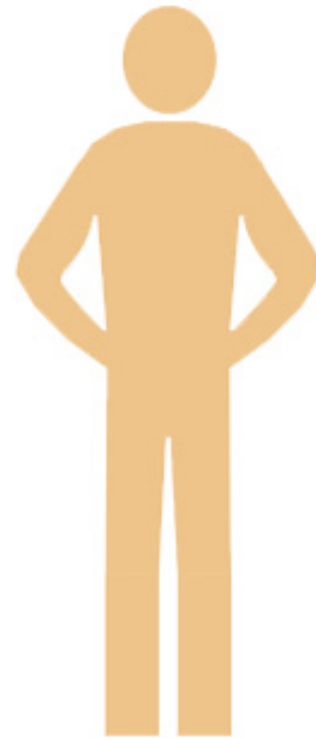
## Funding:

- American College of Physicians Foundation
- Centers for Disease Control

# Where Do Patients Get Information About Their Prescription Medications?



# Sources of Patient Rx Information



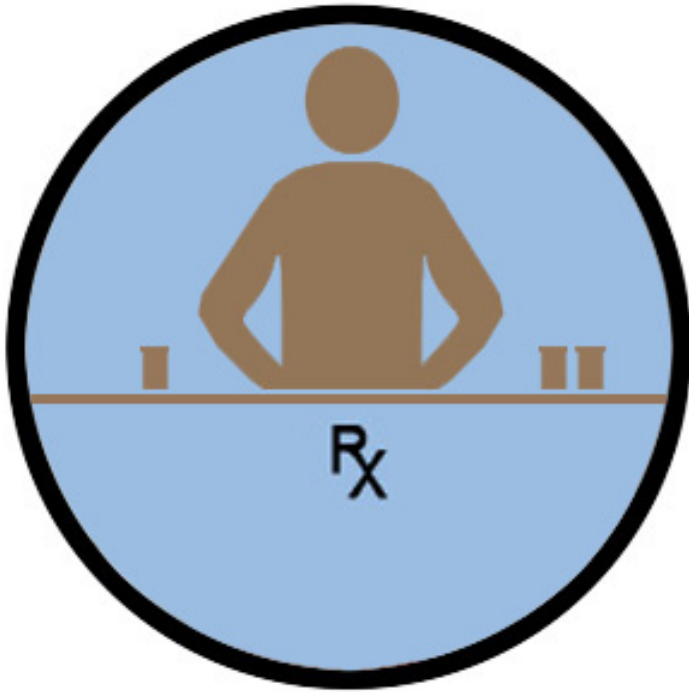
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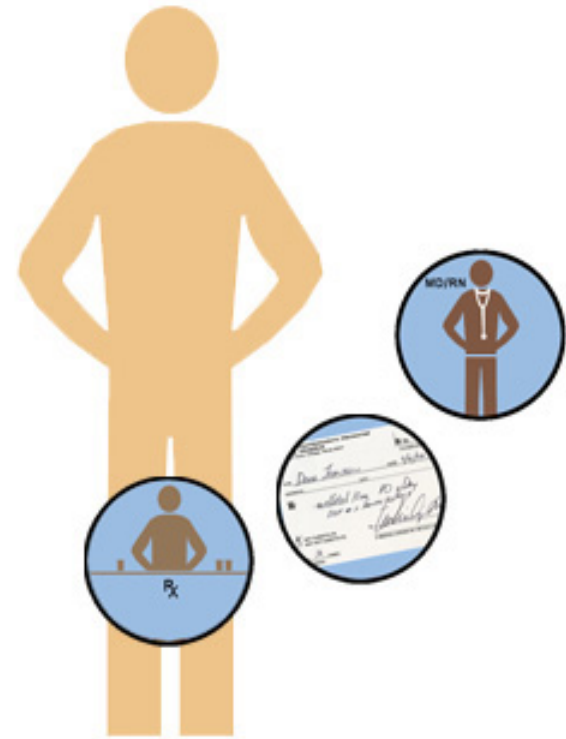
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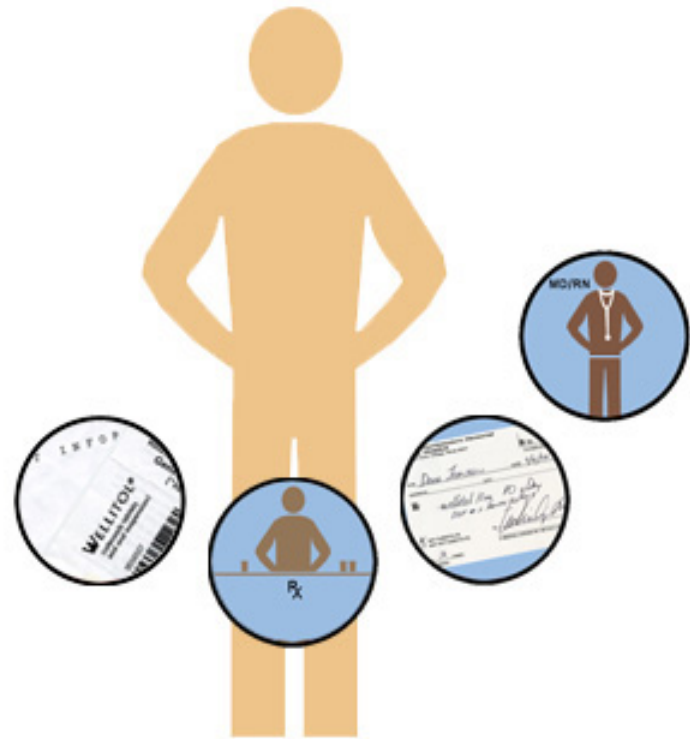


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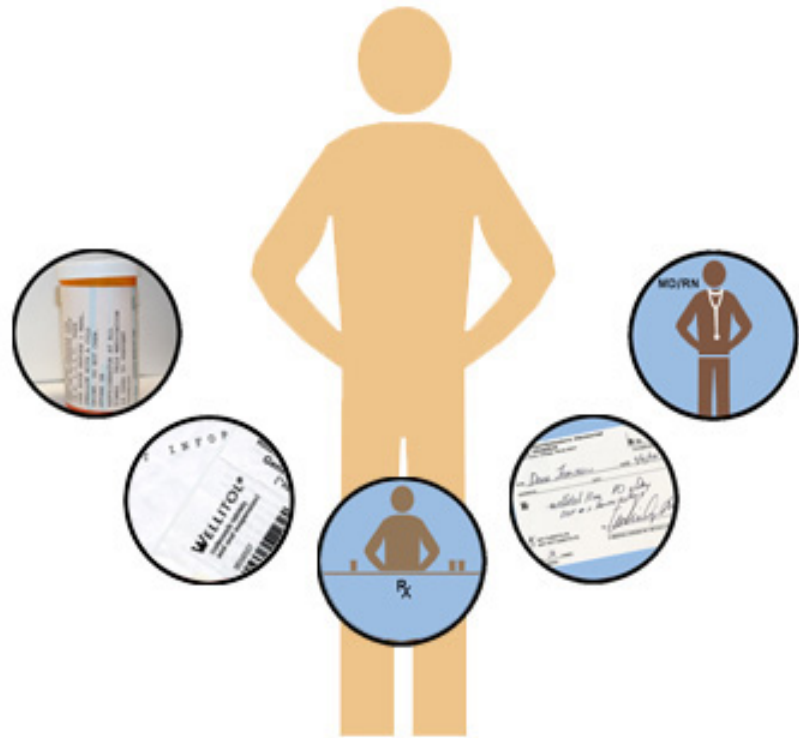




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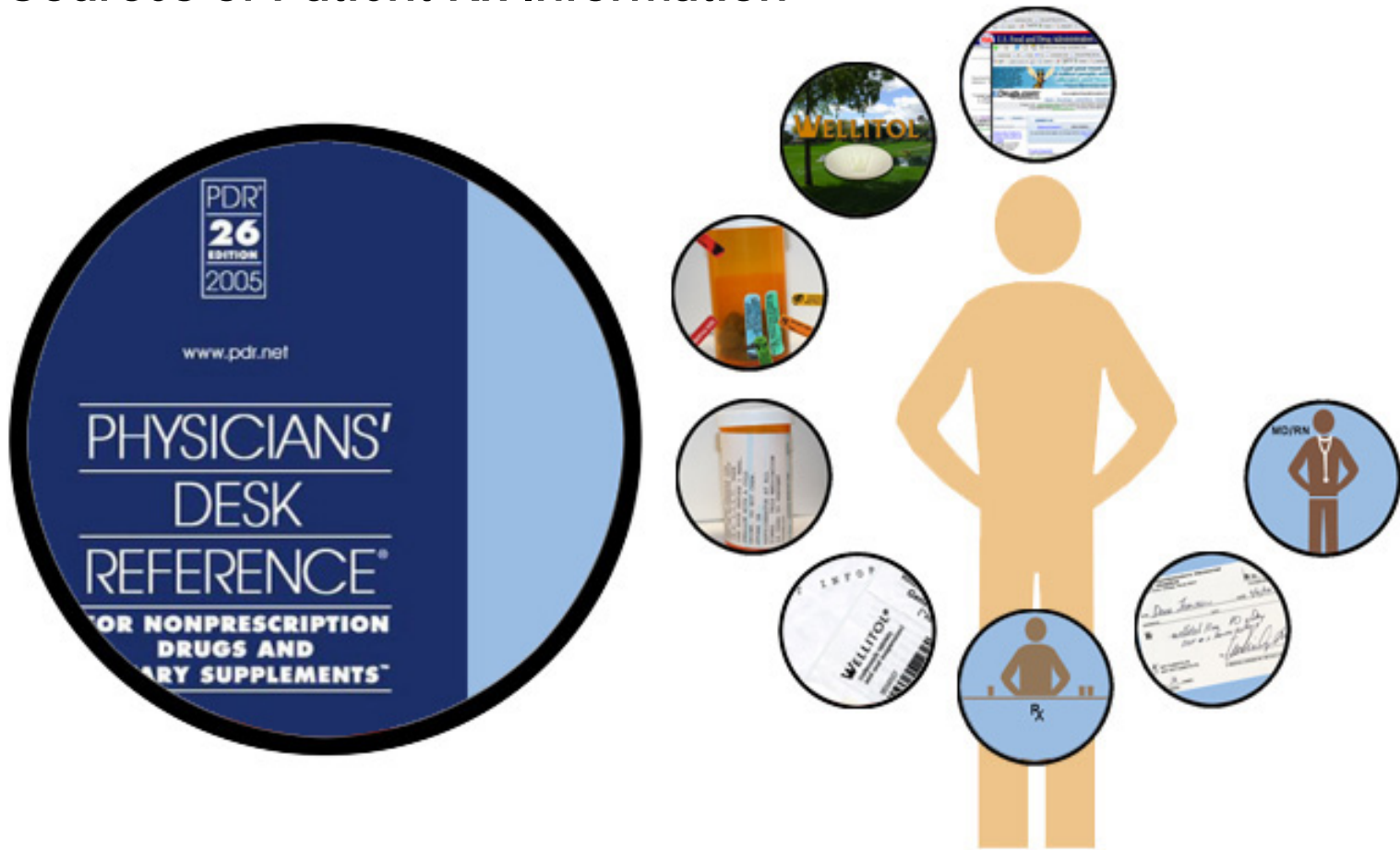
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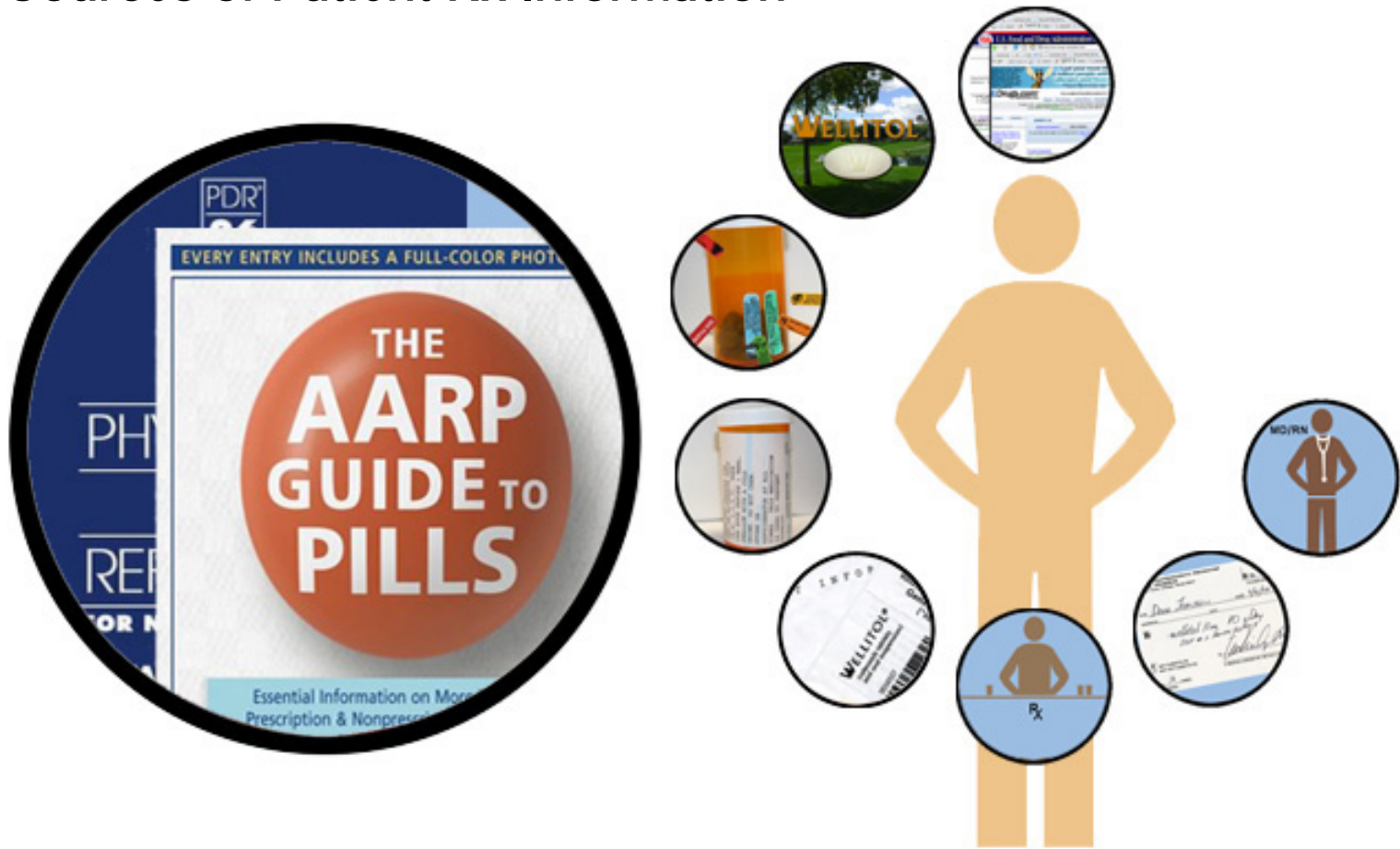
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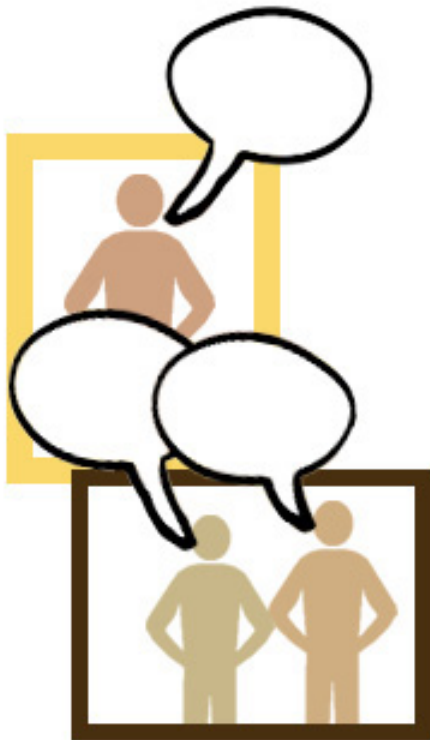


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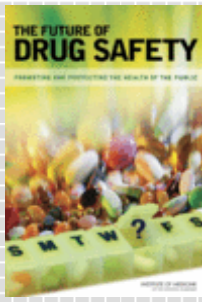
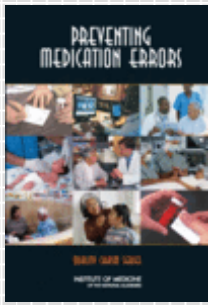




# Standardize, Integrate Patient Health Information Sources







# Recent IOM Reports

## **Preventing Medication Error** (July 2006)

- Existing labeling problems lead to medication errors
- Improve consumer-directed information
- Importance of the provider-patient relationship
- Electronic prescribing as the new environment

## **The Future of Drug Safety** (September 2006)

- New advisory committee on communication with patients and consumers (drug safety concerns)
- Improve information dissemination efforts
- Assure FDA role in regulating/disseminating communications

# The Problem with Med Guides

Wolf, et al. A critical review of FDA-approved Medication Guides. *Patient Education and Counseling*, 2006; 62: 316-322.

- 40 current Med Guides reviewed (April 2006)

## Lexile Analysis

- Average reading difficulty = high school graduate level

## Suitability Assessment of Materials (SAM)

- None deemed adequate for patients with limited literacy
- Problems: content summary, limited scope, graphics

# The Problem with Med Guides

Wolf, et al. A critical review of FDA-approved Medication Guides. *Patient Education and Counseling*, 2006; 62: 316-322.

## Patient Survey

- 251 adult primary care patients, public hospital clinic
- 23% reported having ever looked at Med Guides or accompanying patient information materials.
- Patients with low literacy less likely to review them (17% vs. 33%,  $p < 0.05$ )

# The Problem with Med Guides

Shrank, et al. The variability and poor quality of medication container labels: A prescription for confusion. In press, *Archives of Internal Medicine*, 2007.

- Four prescriptions filled at 96 pharmacies in 4 cities (Boston, Chicago, Los Angeles, Austin)
- One prescription required distribution of Med Guide (ibuprofen, 200mg tablets)
- None of the prescriptions were dispensed with required Med Guide

# Health Literacy Principles in Practice

- Simplify
- Limit and layer information
- Avoid distracters
- Provide context
- Be explicit
- Use patient schema

# ACP Foundation Monograph

- ACPF-Commissioned Monograph (2006)
- Findings of the ACPF Medication Labeling Advisory Committee
  - Academia (Northwestern, Emory, JHU, Harvard, Yale)
  - Agency for Healthcare Quality (AHRQ)
  - Food and Drug Administration (FDA)
  - Institute of Medicine (IOM)
  - U.S. Pharmacopeia

# ACPF Objectives

1. To consolidate an understanding of the broad problem of inadequate patient medication information.
2. To identify a specific course of action to improve drug labeling in the United States.

# ACPF Committee Key Findings

## 1. **Lack of universal standards and regulations for medication labeling a 'root cause' for medication error.**

- *½ million adverse drug events in outpatient settings*
- *Patient misuse of medications common occurrence*
- *Patients have trouble navigating labels, which vary by pharmacy*
- *State boards of pharmacy control label format, not united*
- *Industry-controlled development of patient information leaflets*
- *FDA-approved Med Guides not adequate, or always distributed*

***Patients must be able to learn how to use and recognize labels, both on the container and accompanying medicine***



# ACPF Committee Key Findings

## 2. **Need for an evidence-based set of practices to guide label content and format. Content should be minimized.**

- *Evidence base to determine content inclusion (i.e. warning labels)*
- *Emphasis on information most important to patients*
- *Patient/Consumer input should be sought*
- *Work toward a universal system of medication labeling*

# ACPF Committee Key Findings

**3. Standardize dosage/usage instructions on the container label. Input is needed from pharmacology, medicine, and pharmacy.**

- *Clarity of dosage/usage problematic*
- *High variability exists with dosage instructions.*
- *Building evidence to support explicit instructions*
- *FDA efforts for OTC medications (“Drug Facts”) offer a model*

***Can there be a standard format for R<sub>x</sub> dosage instructions?***

# ACPF Committee Key Findings

- 4. Improve labeling beyond the container, such as Medication Guides and patient information leaflets.**
  - *Assurances needed that Med Guides, leaflets follow design principles supported by criteria for developing health materials (i.e. Doak Method)*
  - *Similar, yet expanded messages as included on container*
  - *Patients/Consumers to be involved in their re-design*

# ACPF Committee Key Findings

**5. Address communication by physicians, nurses, pharmacists, and other relevant health professionals. More training may be needed.**

- *Missed opportunities highlight importance of improved provider communication*
- *Recent FDA actions offer guidance to physicians for patient communication. Is this useful?*
- *Train providers in teachback and other health literacy 'best practices' for patient communication*

# ACPF Committee Key Findings

**6. Research support is needed to move labeling efforts toward an integrated, 'enhanced' approach.**

- *Evidence needed to support inclusion of relevant information only on medication container labels.*
- *More studies to provide explicit guidance to changes in label structure*
- *Can label modifications translate to improved patient knowledge, behaviors, outcomes?*

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