



**U.S. Food and Drug Administration**  
Protecting and Promoting Public Health

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# Patient Information

## The Long and Winding Road

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**Access to useful written patient information is important to ensure appropriate use of prescription medicines**



# Background

- Long history beginning in 1968 when FDA first required prescription patient labeling for estrogens and oral contraceptives
- 1996 – PL 104-180 (CMI)
  - Private sector initiative with collaborative, long-range action plan



# Background

- 1998 –FDA Publishes Medication Guide Final Rule
- 2006 - FDA publishes “Guidance on Useful Consumer Medication Information (CMI)”
- 2008 CMI Final Evaluation Completed
  - 94% of patients received written medication information
  - 75% met minimal criteria for usefulness (Guidance)



# Engaging Stakeholders

- CMI
  - DSaRM AC (7/17/02)
  - Public Meeting (7/31/03)
  - Stakeholder Meetings (12/08-2/09)
- Communication of Drug Safety Information
  - Part 15 Hearing (12/05)
- Medication Guides
  - Part 15 Hearing (6/07)
- Stakeholders Engaging FDA
  - Congress (e.g. FDAAA)
  - Letters, Citizen Petition process



# Where Has the Road Led Us?

- Multiple forms and sources of written patient information
- PPIs
  - Mandatory vs. voluntary
- Medication Guides
  - Inconsistent distribution system
  - Greater numbers than anticipated
  - ?most useful format
  - ?utility, balance and comprehension
- CMI
  - Not meeting statutory goals



# Other Challenges

- Burden to health care system
  - CMI + PPI + Medication Guides =  
too much paper
  - Challenges of electronic distribution
- Assuring value to patients



# What we've heard

- Patients – don't believe they are being informed of risks properly and too much paper is leading to confusion
- Pharmacy – they are overwhelmed with paper requirements creating cost and logistical concerns
- Research is needed to focus on utility, balance and comprehension of Rx drug information with an eye toward reaching the broadest audience possible



# How can you help us?

How do we ensure that prescription drug information is effectively communicated to our target audiences?