

Pregnancy and Lactation Labeling Rule: Targeting the Audience

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LABELS WITHOUT CATEGORIES: A WORKSHOP ON FDA'S PLLR
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Disclosure

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The Practice of Evidence-Based Medicine.....

- ▶ Integrates...
 - ▶ the best external evidence
 - ▶ with individual clinical expertise
 - ▶ and patient preference
- ▶to provide the best care possible for each individual patient

The best external evidence

- ▶ How can the labeling help?
- ▶ By providing the evidence

Who reads the labeling?

- ▶ Doctors

- ▶ Patients

- ▶ Lawyers

Doctors & other prescribers

- ▶ Short attention spans
- ▶ Paper : out Mobile: in
- ▶ Need:
 - ▶ “quick take”
 - ▶ easily identifiable sections

Patients

- ▶ Anxious patients read the labeling
- ▶ All risks are perceived as equal
 - ▶ $1/1000 - 1/10000 = 1/100 - 1/1000 = 1/1 = \text{ME}$

Doctors: What is our role?

- ▶ Google: good for knowledge transfer
- ▶ Doctors: good for knowledge translation

The Labeling Makers: What's your role?

- ▶ Facilitate GOOD knowledge transfer and translation
- ▶ Clear, concise, and clinically relevant
- ▶ Clarify relative risks of drug

Goal: to improve patient care

- ▶ To promote the practice of evidence-based medicine....
- ▶ The labeling must present the best evidence in a clinically relevant and user-friendly way
- ▶ Doctors have the task of explaining why the illness presents greater risks