

**FDA RCAC**

# **Recent theoretical developments**

Ellen Peters

November 17-18, 2011

Silver Spring, MD

# FDA's SPRC

- Strategic Goals
  - Strengthen the science needed to support communications
  - Expand FDA capacity to deliver those communications
  - Optimize FDA policies on communicating risks and benefits

Communication is integral to accomplishing FDA's

mission

# FDA's SPRC

- Strategic Goals
  - **Strengthen the science** needed to support communications (offer research-based recommendations, highlight theory and evidence)
  - Expand FDA capacity to deliver those communications
  - Optimize FDA policies on communicating risks and benefits

# Communication should be evidence-based

- Should reflect the theory and science of risk communication
  - Can point efforts in the right direction

New book: Fischhoff, Brewer & Downs, Eds. (2011). *Evidence-Based Communication of Risk and Benefits: A User's Guide*. Silver Spring, MD: Food and Drug Administration.

# Risk (and benefit) communication

- Concerns more than behavior or behavioral intent
  - There's usually not a “right” choice
- Considering the more complex information processes leading up to informed and value-concordant choices
  - Will help in the design and the evaluation of communications

# To make informed and value-concordant decisions, patients must have:

- Information
  - risks and benefits
  - available, accurate, timely, and complete (but not too much)
- Access the information
- Comprehend the information:
  - Must be able to identify it

Dear doctor letter

8/6/08 Eugene R-G

DR. DONOHUE

# Pain-killing sleep aids are risky

**D**ear Dr. Donohue: I had been taking Tylenol PM every night for more than a year because I had trouble sleeping. Then I saw an ad on television promoting Advil PM as being so much better.

I got 100 tablets and finished taking them, but they were not much better for me. Then I got acid reflux and had trouble swallowing.

Soon after, I tore a knee meniscus and treated myself with aspirin.

A week later, I passed out in a store and was taken by ambulance to the hospital, where I threw up blood. I had a bleeding ulcer and an inflamed esophagus.

I am 86, and I am still trying to regain my health. Why are we not told what ter-

rible things drugs can do?

— C.W.

**Dear C.W.:** Every medicine has side effects, so the less we take, the better off we are.

Advil PM is a combination of ibuprofen — a nonsteroidal anti-inflammatory drug — and diphenylhydramine, an antihistamine. The antihistamine makes many people drowsy and is used as a sleep aid. NSAIDs are among the most widely prescribed and used drugs. They fight inflammation and relieve pain. Advil (ibuprofen), Aleve (naproxen), Indocin (indomethacin) Daypro (oxaprozin), Feldene (piroxicam), Voltaren (diclofenac) and aspirin are commonly used.

These medicines also reduce the production of stomach

mucus, which protects the stomach against the corrosive action of stomach acid and digestive enzymes. Without mucus, those digestive juices can bore a hole (an ulcer) in the stomach lining. That might happen without any warning, or it can be preceded by symptoms such as a gnawing discomfort in the upper abdomen, just below the breastbone.

People older than 60 are at risk for such a side effect, and people older than 75 are greatly at risk. There is a warning on the label, but most people don't read it.

*Dr. Donohue is unable to answer individual letters. Write to him at P.O. Box 536475, Orlando, FL 32853-6475.*

© 2008 North America Syndicate Inc.

# To make informed and value-concordant decisions, patients must have:

- Information
  - risks and benefits
  - available, accurate, timely, and complete (but not too much)
- Access the information
- Comprehend the information:
  - Must be able to identify it
  - And understand and remember its meaning
  - And sometimes remember the verbatim information

CLOSE TO HOME

©2006 John McPherson / DIST. BY UNIVERSAL PUBLISHING INC.

7-10

CLOSETOHOME@GMAIL.COM



"The FDA now requires that we have an actor show you what kinds of side effects you might experience."

# To make informed and value-concordant decisions, patients must have:

- Information
  - risks and benefits
  - available, accurate, timely, and complete (but not too much)
- Comprehend the information:
  - Must be able to identify it
  - And understand and remember its meaning
  - And sometimes remember the verbatim information
- Apply the information:
  - Determine meaningful differences
  - Weight factors to match needs and values
  - Make tradeoffs (e.g., risks and benefits)
- Judgment, decision, or behavior

# Today

- Implications for strategic communication of recent theoretical developments related to FDA's communications

# Science-based communication

- Valerie Reyna
  - Core underlying theory in how people process information in decision making
- Alan Castel
  - Supporting verbatim memory, especially for older adults
- Brian Zikmund-Fisher
  - Importance of identifying goals of communication (patient needs) and tailoring the precision of provided information to those goals