

A Common Sense Approach To Rx Risk Communications

Remarks of Harry Sweeney, Executive Committee Chairman
Coalition for Healthcare Communication

FDA's Communication of Drug Safety Information
Public Hearing Docket No. 2005N-0394
December 7 & 8, 2005
Washington, DC

Three Topics

- How safe are prescription drugs?
- What makes a prescription drug different from a chemical poison?
- What steps do we need to take to help assure an understanding of Rx risks?

How safe are prescription drugs?

David Ropeik · George Gray

of the Harvard Center for Risk Analysis, Harvard School of Public Health

RISK



A Practical Guide for
Deciding What's
Really Safe and What's
Really Dangerous in
the World Around You

Edmund Burke's
**“Precautionary
Principle”**

VS

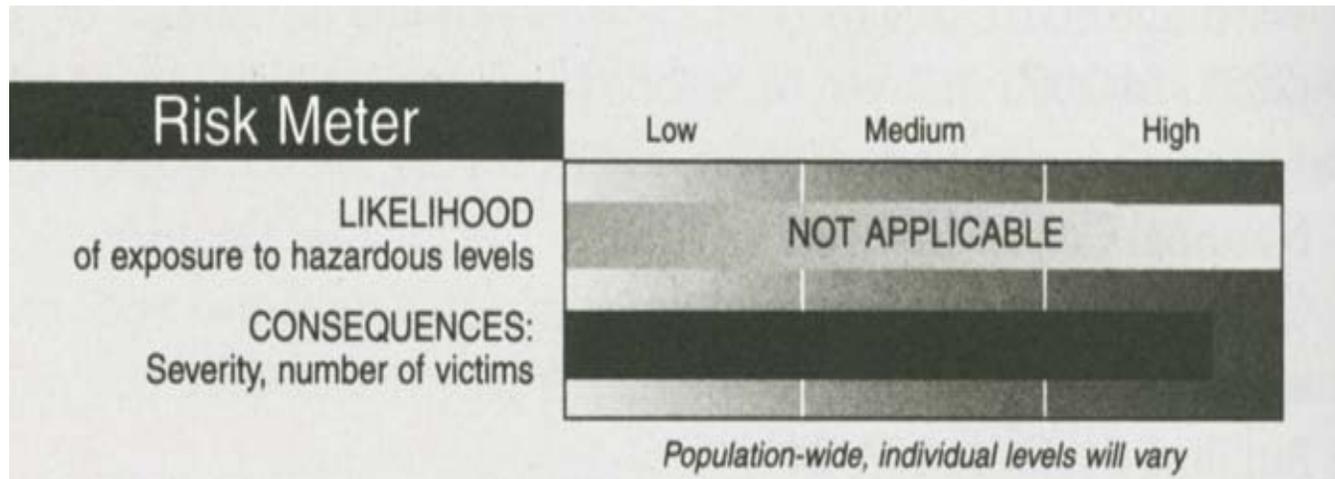
Contemporary
**Risk/Benefit
Balance**

How safe are prescription drugs?

“ Safe enough to make them the fourth leading cause of death in the US.”

**David R Seckman, CEO
Nat'l Nutritional Foods Assn.
citing USA Today May 21, 2001**

Ropeik & Gray “Risk Meter”



- Refers to population as a whole – not to individuals
- Based on estimates – ranges, not scientific facts
- Does not account for, or try to balance benefits
- Based on hazards to which people are exposed
- **Does not explain risks from drug reactions [which] are so unique to each individual that to discuss in a book about risk in general might in fact be dangerous to the reader**

**What makes a Rx drug different
from a chemical poison?**

INFORMATION !

Value of Information

- Reality vs Perception
- Known vs Unknown or Uncertain
- Safe vs Dangerous
- Comfort vs Fear

Familiarity breeds contempt

Speed Kills!

FREAKONOMICS

ROGUE ECONOMIST EXPLORES
THE HIDDEN SIDE OF EVERYTHING

“Prepare to be dazzled.”

— Malcolm Gladwell, author of *The Tipping Point* and *Blink*



NEW YORK
TIMES
BESTSELLER

STEVEN D. LEVITT AND
STEPHEN J. DUBNER

- Information asymmetry (“Expert opinion”)
- “Basic flavors” of incentives
 - Economic
 - Social
 - Moral

What steps do we need to take to help assure an understanding of Rx risks?

- Start low and go slow

Start low and go slow.

- **Prescription Drug Warning Box**

“Prescription drugs are potent medications and should not be taken without specific instructions from your physicians or other health-care professionals.”

- **Standardized icons and an outreach public health program**

A public/private partnership similar to the PAC/FDA anti-quackery campaign of the 1980s

What steps do we need to take to help assure an understanding of Rx risks?

- Start low and go slow
- Understand the barriers

Understand the barriers.

**Why don't people do
what they're supposed
to do?**

Ferdinand F. Fournies Knows

- Consultant, author, former professor, Columbia Graduate School of Business
- Fifteen-year study -- 25,000 people
- “Preventive Management”

Top 10 Reasons People Don't Do What They're Supposed To Do

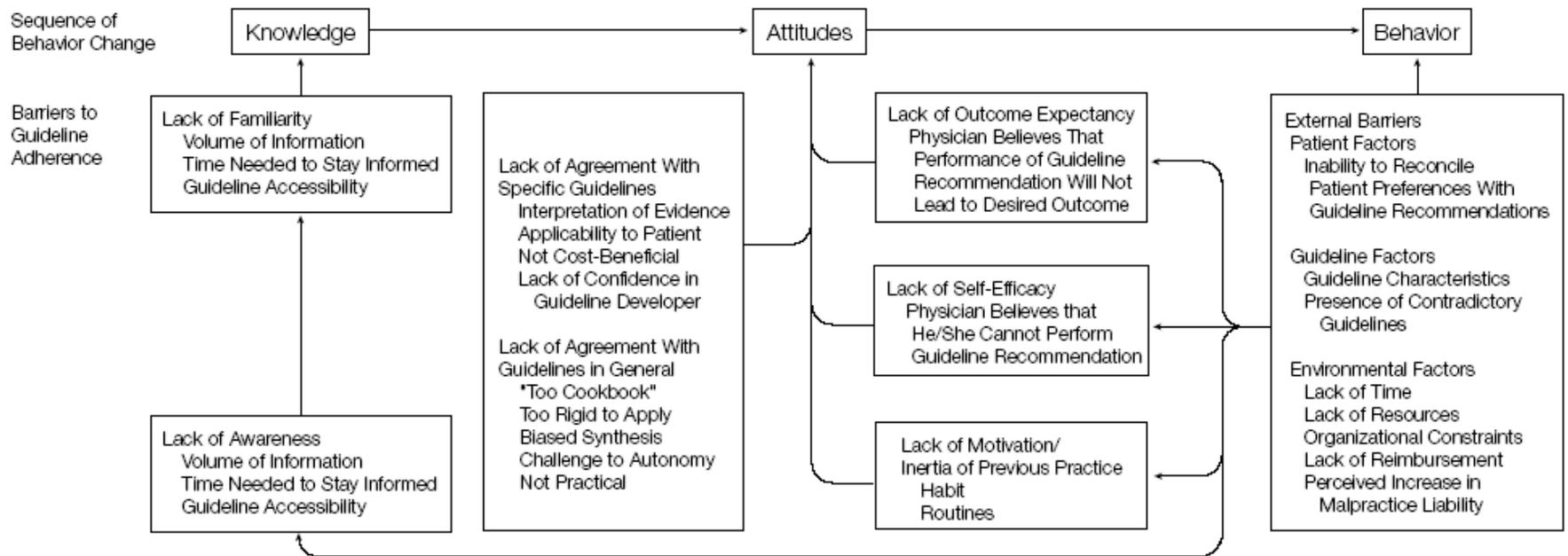
- 10) They don't know why they should do it.
- 9) They don't know how to do it.
- 8) They don't know what they are supposed to do.
- 7) They think your way will not work.
- 6) They think their way is better.

Top 10 Reasons People Don't Do What They're Supposed To Do

- 5) They think they are doing it.
- 4) They are punished for doing it.
- 3) No positive consequences for doing it.
- 2) It's beyond their personal limits.
- 1) No one could do it.

Why Don't Physicians Follow Clinical Practice Guidelines?

Figure. Barriers to Physician Adherence to Practice Guidelines in Relation to Behavior Change



Why Don't Physicians Follow Clinical Practice Guidelines?

1. Lack of awareness
2. Lack of agreement
3. Lack of outcome expectancy
4. Inertia
5. Lack of familiarity
6. Lack of self-efficacy
7. External barriers

Overcome the Barriers

Patient expectations and the clinician's role

“Communication and interaction skills have the most impact on a patient's motivation to litigate . . .”

Source: Communication: A Risk Management Tool JCOM(1999) 6(1):35-38

What steps do we need to take to help assure an understanding of Rx risks?

- Start low and go slow
- Understand the barriers
- Connect the dots

Sandman's Risk Perception Model

RISK = HAZARD + OUTRAGE

“Hazard” = Outcome severity x probability

“Outrage” = Trust, shared control, fairness, and courtesy

What steps do we need to take to help assure an understanding of Rx risks?

- Start low and go slow
- Understand the barriers
- Connect the dots
- Take the time to do it right

Use the “Mental Models” approach.

“This approach relies on interviews with various publics to help identify the information, both correct and erroneous, that people already have (their “mental model”) and then use these interviews and expert knowledge to develop the information people need and want as they attempt to understand a given risk.”