

FDA Risk Communication

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FDA's Mission

- Protect public health
 - assure safety, effectiveness, security of regulated products
- Advance public health
 - speed innovations that make medicines and foods more effective, safer, more affordable
 - help public get accurate, science-based information needed to use medicines and foods to improve health



Products Regulated by FDA

- Foods
- Drugs
- Biologics
 - blood, tissues, non-therapeutic vaccines
- Medical devices
- Cosmetics
- Veterinary & Animal
- Radiation-emitting electronic products



Keyword: Complexity

- Different products, different authorities
 - often within broad product categories
- Organizational structure defined by product categories
- Multiple audiences with differing needs
 - primary audience also differs by product



Foods & Cosmetics

- Only broad product category where
 - primary audience is general public
 - limited pre-market approval authority
- Historical recognition of importance of effective communication to public
 - consumer research was critical input to development of Nutrition Facts labeling



Medical Products

- Historically, communication focused on health care providers
 - in 1500s, physicians fined if they told patients even the names of medicines
 - 1938 *Federal Register* notice: write drug labeling "only in such medical terms as are not likely to be understood by the ordinary individual"
- Significant challenges to FDA attempts to expand labeling to include patients



Clearly, the environment has changed!

Some Significant Changes

- Increasing consumer empowerment and patient advocacy
 - concerns of aging population
 - increased sophistication, expectations
- New and expanded media
- Rapid development of new treatments
 - often with unique complexities
- Recognition of impact of literacy limitations



How do we communicate?

FDA Communicates Indirectly

- Regulation of labels and labeling
 - general public for some products
 - foods, cosmetics, OTC products
 - (mostly) health care providers for medical products
- Regulation of advertisements
 - for prescription drugs & biologics and restricted medical devices
 - otherwise, ads regulated by FTC



But there are limitations

- Some labeling reviewed, some not, before public use
 - "approved" versus "promotional"
- Advertisements generally not reviewed before public use
- Can take enforcement action only if law is violated
 - law often does not address communication issues



FDA Communicates Directly

- Press releases
- Public education campaigns
- Direct response to inquiries
- Variety of tools regarding specific products and product classes (more this afternoon)
- Limitations apply here as well



How effectively are we communicating?

Effectiveness

- Is it too much or too little?
 - when is “more” actually “less”?
- When to communicate?
- What means should we, can we, use?
- How do we know how we’re doing?
- “Everyone’s a critic”



Feedback

- Ongoing, on particular topics, e.g.,
 - direct-to-consumer advertising of Rx drugs
 - notifying the public about emerging risks of medical products
 - health claims on foods & dietary supplements
- Result of direct requests
 - “Future of Drug Safety” IOM report
- FDAAA



December 2005 Public Hearing

- Recommendations on CDER’s risk communication strategies
 - engage health care providers
 - improve internet access for patient information
 - need benefit-risk balance in communications
 - standardize multitude of communication tools
 - address needs of those with low health literacy and poor English skills
- Already addressing some



“Future of Drug Safety”

- Institute of Medicine Report about drug safety in general
- “Communicating about Safety” chapter
- Two recommendations
 - CDER should develop a cohesive risk communication plan
 - Congress should establish FDA advisory committee on communication with patients and consumers



Risk Communication Advisory Committee: Function

- Advise FDA on strategies and programs to communicate with the public about the risks and benefits of regulated products to facilitate optimal use
- Review and evaluate relevant research
- Facilitate interactively sharing risk and benefit information with public to enable people to make informed independent judgments about use of regulated products



Risk Communication Advisory Committee: Composition

- Composition different from most Advisory Committees
- Importance of including the perspectives of our varied real-world audiences
 - “experiential insight on the communication needs” of the users of FDA-regulated products
- Ramifications of coverage of multiple products



Risk Communication Advisory Committee: Focus

- General practices and processes
 - overall needs of different audiences (patients, consumers, providers, media, industry)
 - internet
- Issues relevant to large product categories
 - foods vs. medical products
 - maybe different medical products, e.g., regarding consumer-directed advertisements



The Long View



More Immediate View

- Today
 - AM: FDA's authorities and constraints on our activities and a little about FDAAA
 - PM: open public hearing, followed by key FDA risk communication activities and discussion of possible scenarios
- Tomorrow's focus is recall press releases
 - AM: background and open public hearing
 - PM: committee discussion

