



Risk Communication Science at FDA: One Person's Perspective

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Beginnings – Communication*

- *Caveat
- Limited agency-level rollouts
- Medical product center level foci
 - health care professionals
 - indirect through regulation
 - labeling
- Food center foci
 - consumers
 - safe use education
 - labels

Beginnings - Research

- Center for Food Safety and Applied Nutrition (CFSAN) research focused on consumers
 - infant feeding practices; food consumption studies
 - beliefs about nutrition and health impact
 - safety regarding food preparation and individual vulnerabilities
 - Nutrition Facts label development
- Center for Drug Evaluation and Research (CDER) research focused on patients and health care professionals
 - prescription drug labeling and information
 - prescription drug advertising

Selected Drug-Related Research: ± '90s

- Receipt of oral and written prescription drug information at pharmacies and doctors' offices (repeated national patient surveys; sponsorship of assessment of Consumer Medication Info.)
- Assessment of use and usefulness of prescription drug labeling (with physicians)
- Consumer understanding of prescription drug advertising claims
- Consumer and physician beliefs about direct-to-consumer prescription drug advertising (surveys)

New Decade

- Increasing policy-related attention leads to more support for research out of CDER's Division of Drug Marketing, Advertising, and Communications (DDMAC)
 - influence of prescription drug advertising on both the public and prescribers
- Infusion of funding and staff for research to support policy-related decisions
- Selected research:

www.fda.gov/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/default.htm

Internal and External Influences

- December 2005 public hearing on drug-related risk communication strategies
- Institute of Medicine 2006 “Future of Drug Safety” report
 - chapter focusing on communicating about safety
 - recommendations that Congress to establish an external advisory committee and FDA produce a cohesive risk communication plan for drug safety

FDA's Response

- Spring 2007 Establishment of Risk Communication Advisory Committee (RCAC)
 - 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

2007 FDA Amendments Act

- Mandated establishment of “Advisory Committee for Risk Communication”
- Mandated that FDA ask committee for advice on certain issues
 - specific studies related to direct-to-consumer (DTC) advertising of prescription drugs
 - FDA drug safety website
- Mandated that FDA request advice from risk communication and other experts on other topics

RCAC Meetings & Topics

- February 2008 first meeting
 - overview of FDA risk communications and context, committee's charge, draft recall press release
- On average, 3 meetings annually
- Variety of topics including
 - science of risk communication
 - food-borne outbreaks
 - emerging risk information
 - NIH clinical trials database
 - prescription drug information
 - DTC advertising research

RCAC Recommendations

- Consistent and frequent emphasis on empirical testing
 - for communication effectiveness, because target audiences do not conform to expert expectations, intuition, or “common sense”
 - for cost effectiveness, to avoid spending scarce funds ineffectively
- Need to strategically plan and build in communication considerations from the outset
 - develop tested templates for similar communications
 - pretest, even if informally, if templates not available

FDA's Further Responses

- Establish OC staff focused on risk communications
- Issue Strategic Plan for Risk Communication (SPRC)
- Fund research to evaluate value of social media
- Develop generic clearances to streamline PRA research clearance hurdles
- Establish Internal Informal Message Testing Network
- Complete and use recall press release template
- Establish mechanism for quick turn-around assessment of public responses

Strategic Plan for Risk Communication

- 3 overarching goals: science, capacity, policy
- 14 strategies
- 70+ actions
- commitment to completing 14 specific actions within first year

Cross-Agency Commitment to Gathering Evidence

- Funding for applied research
 - assess value of social media
 - understand how people make decisions about specific product use
- Supporting evaluation/research mechanisms
 - polling capacity for public health emergencies
 - examining social media-based public responses
 - HINTS questions & FDA National Consumer Survey
- Streamlining research clearance processes
- Using internal message testing mechanism
- Finalized public research needs document
 - working with NCI to encourage research in specific areas

Other Supportive Activities

- Risk communication “perspective” included in major rollouts
- Feedback mechanisms in greater demand
 - plan to evaluate
- Implementation of Strategic Plan for Risk Communication incorporated into FDA’s Strategic Priorities (2011-2015) document
- Continuing collaboration with HHS and cross-FDA Health Literacy Workgroup





Thank you!!