

# FDA's Risk Communication Research Agenda

The purpose of this agenda is to describe topics in risk communication research that are important to the U.S. Food and Drug Administration (FDA). We hope this agenda will encourage outside researchers to consider questions related to risk communication that will help further FDA's public health mission, as well as inform others interested in the field of risk communication. We believe this will be especially useful for researchers outside FDA in the social, psychological, and decision sciences, communications, health education, and related fields who may be interested in pursuing topics that can have positive effects on public health while furthering scientific knowledge.

This agenda represents FDA's current assessment of high priority research needs for improving how we communicate about the products we regulate. We encourage researchers to contact us with questions (see the section below on Technical Assistance). We also welcome information about research on related topics not currently listed here. We will modify this agenda in the future as appropriate.

We believe that issuing this agenda will increase FDA's transparency and illustrate what we see as most needed in risk communication research. By clearly stating our research priorities we also hope to engage non-FDA researchers interested in conducting risk communication research.

## FDA Risk Communication Research Needs at a Glance, September 2010

- **Knowing our Audience(s):** Depending on who the audience may be, determine what, when, and how the audience needs to receive risk information.
- **Reaching our Audience(s):** Identifying avenues to amplify FDA's messages, from partners in spreading the word, to technological channels.
- **Ensuring Audience Understanding:** Presenting the available information clearly, even when important facts may be unclear and/or changing.
- **Evaluating Effectiveness of Communications about Regulated Products:** Identifying methods to test and improve how well we communicate.

## ***Background***

Researchers and communication practitioners from across FDA worked together to identify our priority risk communication research needs, with the understanding that risk communication is about interactively sharing risk and benefit information to enable people to make informed judgments about use of FDA-regulated products. Some of these research needs are general and others are specific to certain product categories.

This agenda is one product of FDA's development and implementation of its overall [Strategic Plan for Risk Communication](#) (SPRC), released in September 2009. One of the actions highlighted for early attention was, "produce a research agenda for public dissemination and provide technical assistance and other support to facilitate research."

FDA's Risk Communication Research Agenda (Research Agenda) describes the research we think is most needed to achieve one of the major goals of the SPRC—to strengthen the science that supports

effective risk communication. The Research Agenda builds on existing research on risk communication to highlight gaps of specific importance in FDA's work. Research in the areas listed will address questions about the needs of our target audiences, how to best respond to these needs, and how to anticipate and assess the results.

FDA promotes research in risk communication internally and externally in various ways.

- FDA conducts its own research, often contracting out the actual data collection.
- FDA designs and contributes items to add to surveys sponsored by others.
- FDA conducts collaborative research with non-FDA government and non-government scientists.
- FDA provides technical assistance for research designed and conducted by others.

For more information about recent and ongoing FDA research related to risk communication, please visit the links on the [FDA Risk Communication page](#).

## ***Technical Assistance***

Our Strategic Plan called for us to not only “produce a research agenda for public dissemination,” but to also “provide technical assistance and other support to facilitate research.”

FDA provides technical assistance by making experts available to give information about our programs, regulations, and procedures. Researchers often request such information from us to ensure that the design and analysis of their research will reflect and apply to real world conditions.

We are happy to provide technical assistance to the extent our resources allow. However, it is important to understand that in providing such assistance we are not causing the research to take place or to be conducted in any particular way.

Please see the appendix for information on how to contact us for technical assistance.

## ***FDA Risk Communication Research Needs, September 2010***

The topics listed in the box titled FDA Risk Communication Research Needs above are expanded on in the subsections below. This is a snapshot of our priority research needs at this time (Fall 2010). We expect these needs will evolve with time.

### **Knowing our Audience(s):**

- **When is communication needed?**
  - When do consumers, patients, and caregivers want to know about emerging risks of products they use?
    - As soon as there is a suspicion?
    - Not until a link has been established between a problem and a product?
    - Not until there is a firm recommendation about how to manage the risk?
  - In communicating with different audiences about emerging risks, what is the most important information to communicate early in the evolving situation?
- **From where is the audience starting?**
  - How do experts such as health care professionals and other members of the public, such as consumers, patients, and caregivers, generally think about the risks and benefits of medical products, foods, tobacco products, and other FDA-regulated products?

- What models best describe the thinking of experts and of other members of the public in consumer, patient, and caregiver roles? How are they similar and how do they differ?
- How do experts such as health care professionals, and other members of the public, such as consumers, patients, and caregivers, integrate new information into their existing belief structures about the risks and benefits of medical products?
- What do people who do not currently use tobacco products think about them?
- **What information is needed in a communication?**
  - What can we learn from existing research about how best to meet the information needs of health care professionals, consumers, patients, caregivers, and other significant audiences?
  - What information do consumers, patients, and caregivers need to make good use of medical products, including biologics, medical devices, and both prescription and nonprescription drugs?
  - What information do consumers need to make good use of nutritional information, as in the food label?
  - In the case of food product recalls, what information do consumers and caregivers need to understand the recommended actions?
  - What information do consumers need to understand the hazards of tobacco product use?
- **What motivates audiences to take action?**
  - Some FDA communications support decision making by providing information that members of the public can consider along with their own values and needs. Other FDA communications make specific recommendations for actions, such as locating and disposing of certain recalled food products or avoiding certain drug/drug or drug/diet combinations. In situations where we must motivate action, how can we be most effective?
  - What motivates (and what discourages) people to take action on:
    - Product recalls and warnings?
    - Notices of FDA's suspicion of problems or emerging, uncertain information?
    - Health information such as dietary recommendations related to weight loss/maintenance or warnings about the use of tobacco products?

## Reaching our Audience(s):

- **What are the background attitudes of audience segments?**
  - What level of trust do different audiences have in different types of information FDA disseminates?
  - How does trust compare among audience segments: health care professionals, consumers, caregivers, media, other?
  - What attitudes, other than trust, affect how audiences receive FDA messages?
  - What prior beliefs about regulated products do communications need to address?
- **What partners would amplify FDA's messages?**
  - Who are the potential trusted sources among traditional media?
  - Who are the potential trusted sources among recently developed and emerging media?
- **What communication channels or tools are most effective for FDA to deliver information in a form useful to the public? Examples include:**
  - Web Pages
  - Public Service Announcements/broadcast news
  - Print Media
  - Social Media
    - What is the impact on different audiences of social media tools for amplifying and disseminating critical information?
    - What audiences are best communicated with through which social media tools?

- How can social media tools be used to obtain ongoing feedback on the effectiveness of particular communications?

## Ensuring Audience Understanding:

- **What message content is most effective?**
  - Under what circumstances would it be more effective to frame a message as involving a risk-risk comparison versus framing the message as a risk-benefit comparison? For example, suppose a risk-risk comparison addresses the risk of using a product compared to the risk of not using the same product, while a risk-benefit comparison addresses the risk(s) of using a product against the potential benefit(s) of using the product.
  - How can FDA most effectively communicate to different audiences that the information about a particular product or issue is continuing to accumulate and that circumstances could change, and therefore they should not take hasty action but should “stay tuned” for updates?
  - How can FDA most effectively communicate to inform and to motivate where appropriate but not to cause excessive alarm?
  - How should we measure the messages that are being communicated to the public by an ad, given that in fulfilling our obligation to ensure that prescription drug advertising is “balanced,” we must examine not just the intent of an ad, but evidence of the ad’s practical effect?
  - How can FDA communicate effectively when the affected public must initially dispose of a recalled contaminated food product, but in the long run should continue eating the food after the recall is over? What information do consumers and caregivers need to know that a recall is over and that what they find in the market place is new product?
  - How often and in what ways should we change messages to ensure that people continue to pay attention to advice that is not new but continues to be important?
- **What message formats are most effective?**
  - How can FDA most effectively communicate to different audiences the uncertainties associated with emerging science so they can appropriately include this in their decision making? (Narrative, graphics, tables, other?)
  - How can we communicate more effectively about regulated products with audiences who differ in language or cultural cognitive models associated with health and medicine? Would it be more effective for FDA itself to bridge these gaps by tailoring communications to its different audiences, or to enhance efforts to reach family or community helpers who might be better able to bridge the gaps?
- **What is the impact of jargon and terms of art?**
  - How do different audiences perceive the meaning of “term of art” words, phrases, and disclaimers commonly used in FDA communications? These terms often have special legal importance. However, are there alternatives to misunderstood “term of art” words and phrases that would facilitate understanding? Also, do different audiences understand the alternatives as intended?

### Examples of terms to evaluate:

- Safe and effective
- GRAS, GRAE (Generally Recognized As Safe, Generally Recognized As Effective)
- Product recall, or voluntary recall
- Product correction
- Dietary supplement disclaimer, “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”
- “Safety First”
- Population health

- **How should we address numeracy in communications?**
  - What is the impact of differing levels of health literacy and numeracy on the effectiveness of including quantitative information about risks and benefits in information for consumers, patients, and caregivers?
  - Should quantitative information about the benefits and risks of FDA-regulated products be included in messages about those products? If so, how should it be presented?
  - If information should be tiered (for example, presented in summary followed by sections in more technical depth), how should it be tiered?
  - What numerical presentations are most useful for those who communicate with patients, including health care providers, health educators and informal care-givers such as family members?

## **Evaluating Effectiveness of Communications about Regulated Products**

- **What is the impact of FDA communications?**
  - To what degree are recall communications and activities reaching, and being noticed by, targeted audiences?
  - To what degree are recall communications and activities understood by targeted audiences?
  - To what degree do recall communications and activities result in targeted audiences taking the recommended action(s), such as removing products from shelves?
  - How effective are existing tools that FDA uses to communicate known product information (for example, nutrition labels and package inserts) versus emerging product information?
  - What long-term effect(s) do recalls or warnings associated with a contamination or outbreak have on consumer perceptions of a food substance or product?
- **What audience and product characteristics affect FDA communications?**
  - To what extent are people getting, or likely to get, habituated to recalls or emerging risk information about FDA-regulated products, and consequently start paying less attention to such information?
  - Are there differences in habituation or “fatigue” with different channels of communication?
  - Does the impact of recalls or food/feed contamination warnings on product perceptions differ as a function of whether the affected food is for humans, pets, or livestock?
  - Are certain products perceived as always problematic or always safe? Is this because of prior recalls or warnings? Is the perception affected by recalls or warnings?
  - What subgroups’ needs should we address first for the greatest potential of measurably improved understanding leading to improved health outcomes?
  - What levels of risk will audiences accept for different products?

## Appendix: Contacting FDA for Technical Assistance

If you are considering research about the following topic areas, please feel free to contact us to discuss technical assistance. If you are considering research in an area not listed below, please call 1-888-INFO-FDA (1-888-463-6332).

Foods and Cosmetics	<a href="mailto:Consumer@fda.gov">Consumer@fda.gov</a>	1-888-SAFEFOOD
Human Drugs:	<a href="mailto:druginfo@fda.hhs.gov">druginfo@fda.hhs.gov</a>	301-796-3700
Medical Devices and Radiological Health:	<a href="mailto:dsmica@fda.hhs.gov">dsmica@fda.hhs.gov</a>	1-800-638-2041 or 301-796-7100
Vaccines, Blood, & Biologics	<a href="mailto:ocod@fda.hhs.gov">ocod@fda.hhs.gov</a>	1-800-835-4709 or 301-827-1800
Animal and Veterinary Products:	<a href="mailto:AskCVM@fda.hhs.gov">AskCVM@fda.hhs.gov</a>	240-276-9300
Tobacco Products:	<a href="mailto:askCTP@fda.hhs.gov">askCTP@fda.hhs.gov</a>	1-877-CTP-1373
Toxicological Research	<a href="mailto:NCTRinformation@fda.hhs.gov">NCTRinformation@fda.hhs.gov</a>	1-870-543-7000