Risk Communication Advisory Committee
Meeting: April 30 – May 1, 2009
Discussion Topics

Capacity Goal: Expand FDA's Capacity to Generate, Disseminate, and Oversee Effective Risk Communication

- After reviewing the Capacity Goal of the draft RC Strategic Plan,
  (a) What strategies could be further clarified to better support this goal?
  (b) What strategies might we consider adding for this goal?
  (c) What additional scientific questions need to be addressed to meet this goal?

- The strategies for our Capacity Goal include several for streamlining processes for research and testing (e.g., pilot testing a subset of cases, and/or testing messages with FDA staff not involved in the topic). This reflects the need to balance getting timely results against getting data that we are confident will be reliable and can be extrapolated to critical population segments. What types of questions can we reasonably answer through using in-house "surrogate" audiences or variations on standard customer satisfaction surveys or focus groups (that can be implemented relatively quickly), versus the questions we should examine with larger or more representative samples? Please provide suggestions or examples about approaches that would most effectively capture both ends of the spectrum.

Policy Goal: Optimize FDA's Policies on Communicating Product Risks and Benefits

- After reviewing the Policy Goal of the draft RC Strategic Plan,
  (a) What strategies could be further clarified to support the goal?
  (b) What strategies might we consider adding to the goal?
  (c) What additional scientific questions need to be addressed to meet this goal?

- As noted in Policy Strategy 2, one aspect of FDA's commitment to transparency has been to make information about emerging risks of the products we regulate available sooner; accordingly, our research priorities include learning how "soon" patients, consumers, and experts want to learn about emerging risks. To help inform this effort, please identify any existing research regarding the consequences of communicating early such emerging information about FDA-regulated products. What methodological approaches could be used to help develop or further refine an answer to the question of when to communicate with different audiences about still-uncertain risks? In your comments, please address how the optimal timing may be influenced by the nature of emerging risk information, which may represent: a previously unknown risk; a risk that may (or may not) be clinically relevant for most patients or consumers; or the information itself may reflect data of poor quality and consequently indeterminate risk.

Science Goal: Strengthen the Science Supporting Effective Risk Communication

- After reviewing Science Goal of the draft RC Strategic Plan,
  (a) What strategies could be further clarified to support the goal?
  (b) What strategies might we consider adding to the goal?
  (c) What additional scientific questions need to be addressed to meet this goal?

- In addition to the list of research categories and priorities for the FDA, we hope researchers outside the FDA will also help fill gaps in key areas of risk communication knowledge; please provide suggestions or examples of ways to encourage researchers outside of FDA to pursue the proposed research ideas (with non-FDA funding).

Research Categorization and Priorities:

- After reviewing the proposed Research Categorization and Priorities appended to the draft RC Strategic Plan,
  (a) What research questions could be further clarified to support FDA's Risk Communication Strategic Goals as described in the draft plan?
  (b) What types of research or research questions might we consider adding to this listing?
  (c) What types of research or research questions currently listed could be informed (or even answered) by existing research? Please provide as much detail as possible.

- The RCAC has noted that members of the public may perceive the meaning of "term of art" words and phrases very differently from either the legal context from which they arise or FDA's intended meaning. The FDA recognizes the need to test how people do in fact understand several key terms. What existing research would inform the decision of whether to provide public education about such terms or change terms (where change is legally possible)?

Overall:

- After reviewing and discussing our draft RC Strategic Plan,
  (a) What further clarifications would you recommend that we consider?
  (b) What further strategies would you suggest we consider adding to the plan?
  (c) What further comments, examples, or references to published research, would you suggest to us, regarding this draft strategic plan and research agenda on risk communication at the FDA?