



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

Jeffrey Shuren, M.D., J.D., Associate  
Commissioner for Policy and Planning

April 30, 2009

# Context for Policy Goal

- Work is ongoing – we are renovating our fire station at the same time as we fight fires and champion fire safety
- Must have appropriate policies in place to facilitate progress on goals to expand capacity and strengthen science

# Strategies to Optimize FDA's Policies - 1

- Develop principles to guide consistent & easily understood FDA communications
  - what information should be consistently included?
- Identify consistent criteria for when and how to communicate emerging risk information

## Strategies to Optimize FDA's Policies - 2

- Re-evaluate and optimize policies for using partnerships and other leveraging activities to facilitate effective communication about regulated products
  - sharing information; addressing needs of medical professionals
- Assess and improve FDA communication policies in areas of high public health impact

# High Public Health Impact: Examples

- Modernize effective communication in a recall
- Ensure that patients get useful written information about the prescription drugs they use
- Ensure that medical professionals get useful information about FDA-regulated products when and in the form they need it
- Modernize the regulation of prescription drug promotion

# Discussion Topics - 1

- After reviewing the draft Policy goal and strategies
  - (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?

# Discussion Topics - 2

- Please identify and discuss any principles or recommendations, derived from existing research, for when it is most appropriate to communicate with different audiences about still uncertain (emerging) risks of FDA-regulated products.

# Discussion Topics - 3

- Assuming that FDA would at least pilot such principles, what kinds of testing or evaluation would be most effective to address the question of when to communicate to maximize public health outcomes.
- In your comments, please consider that emerging risks may be previously unknown and may (or may not) be clinically relevant to most patients or consumers – also, that the relevant information may reflect poor quality data and thereby contribute to the indeterminacy of the risk.



# Questions and Discussion