



Strategic Planning at FDA

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Overview

- Brief safari through the strategic planning literature
- Strategic planning in public organizations
- Strategic planning in the federal government
- Strategic planning at FDA
- FDA's Strategic Action Plan
- Development of the Risk Communication Strategic Plan

What is strategy?

- Henry Mintzberg's 5 Ps
 - **Plan**: a consciously intended course of action
 - **Pattern**: consistency in behavior over time
 - **Position**: a niche in a competitive environment
 - **Perspective**: an ingrained way of perceiving and responding to the environment
 - **Ploy**: a stratagem in a competitive situation

What is strategic planning?

- John M. Bryson:
 - “[Strategic planning is] a disciplined effort to produce fundamental decisions and actions that shape and guide what an organization is, what it does, and why it does it.”
 - “To deliver best results, strategic planning requires broad yet effective information gathering, development and exploration of strategic alternatives, and an emphasis on future implications of present decisions.”

Strategic Planning for Public and Nonprofit Organizations, Jossey-Bass (Wiley), 1995

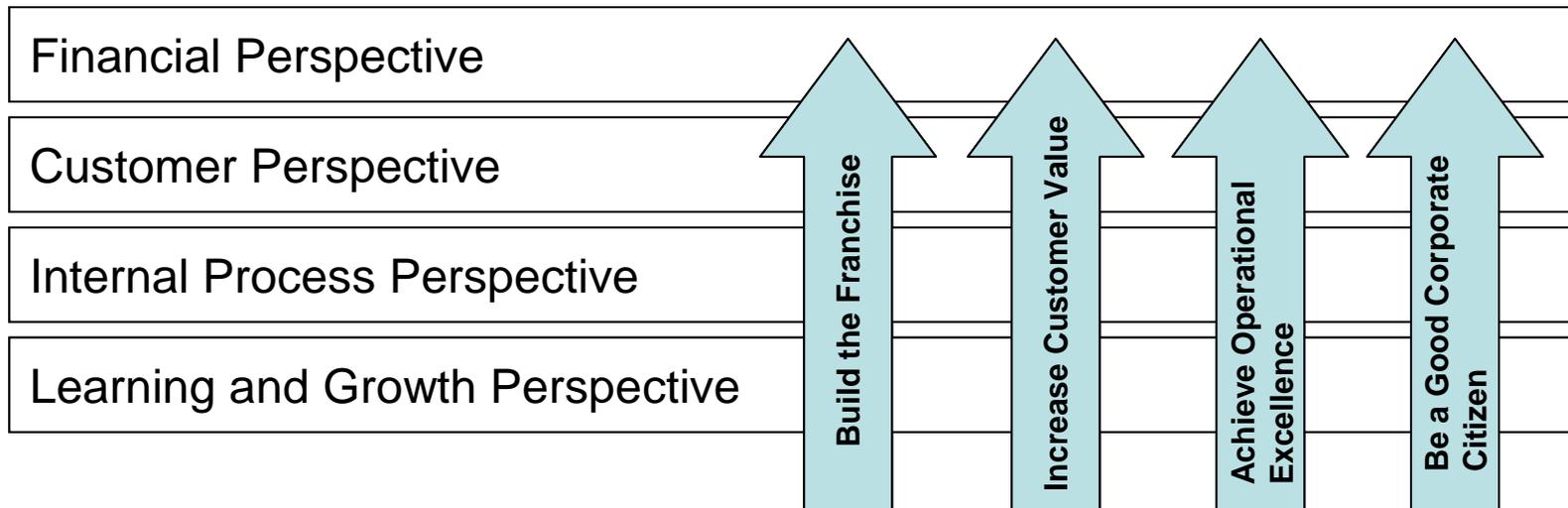
Ten Schools of Strategy Formation

Mintzberg, Ahlstrand, and Lampel, *Strategy Safari: A Guided Tour Through the Wilds of Strategic Management*, New York: The Free Press, 1995

- **Design:** a process of *conception* (SWOT)
- **Planning:** a highly *formal*, structured process
- **Positioning:** an *analytical* process (market niche)
- **Entrepreneurial:** a *visionary* process
- **Cognitive:** a *mental* process
- **Learning:** an *emergent* process
- **Power:** a process of *negotiation*
- **Cultural:** a *collective* process
- **Environmental:** a *reactive* process
- **Configuration:** a process of *transformation*

Strategy and Measurement

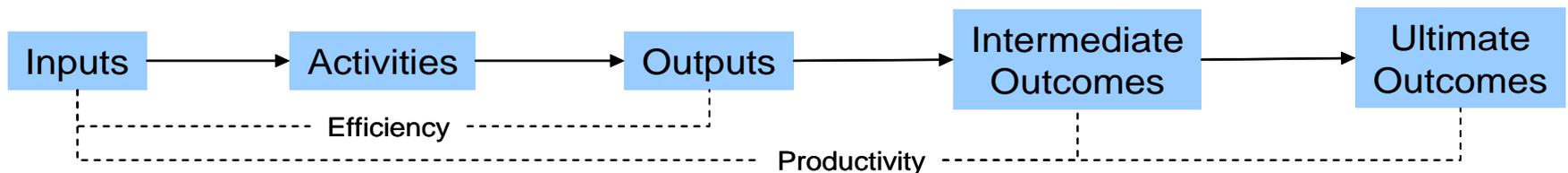
- **Balanced Scorecard of Kaplan and Norton**
The Strategy-Focused Organization, Harvard Business School Press, 2001
 - Architecture of a Strategy Map:



Measurement Along the Strategic Value Chain

- **Inputs** – resources needed to carry out FDA’s mission
- **Activities** – FDA regulatory and business processes or services that produce outputs
- **Outputs** – the immediate results of FDA activities used by customers or stakeholders
- **Outcomes** – related to the consequences of FDA outputs in the world, or the results that matter to the public, which often depend on factors beyond FDA’s control
 - Intermediate outcomes
 - Ultimate outcomes

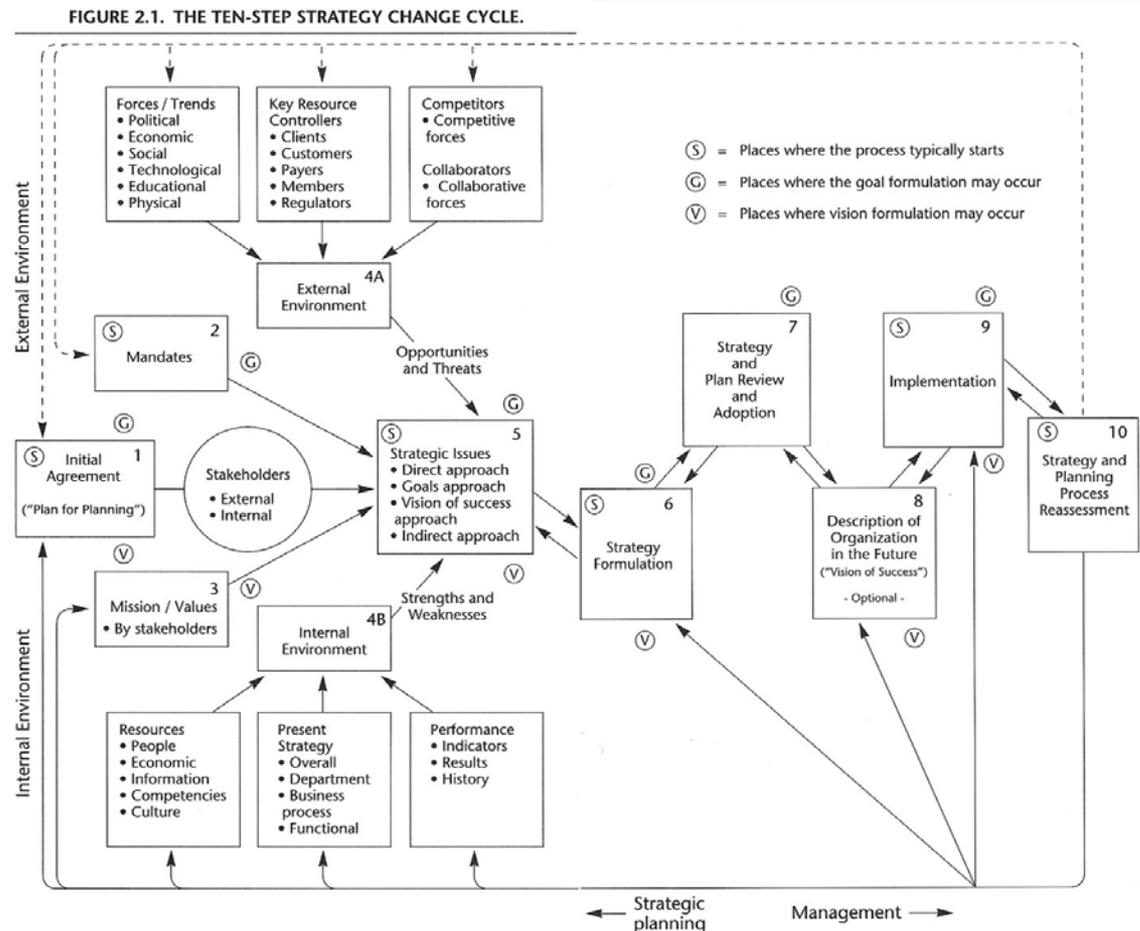
Measures help us understand how well our work improves public health



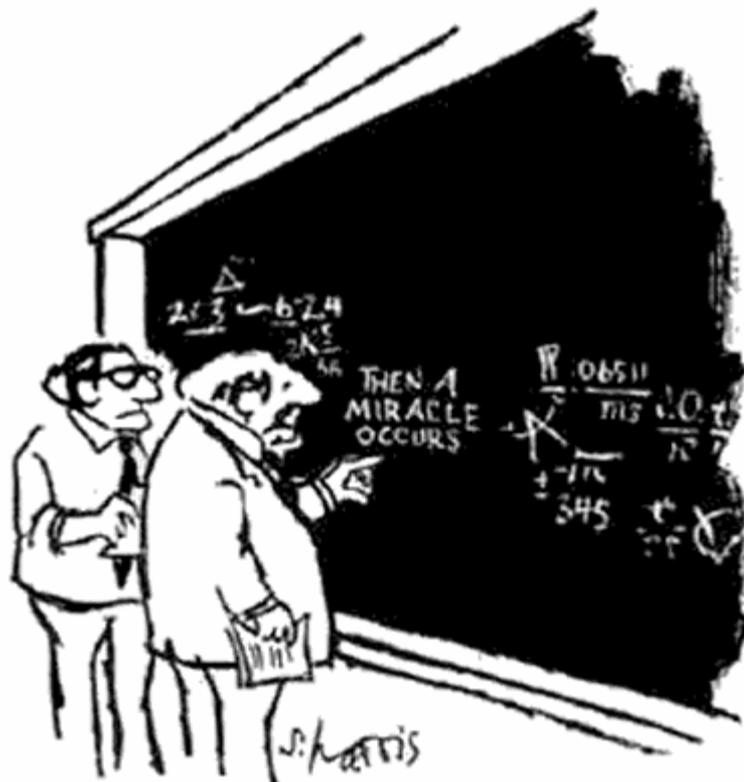
Bryson's Model for Strategic Planning in Public Organizations

Simplified Overview

- Gather and analyze information to identify Strategic Issues
- Formulate strategy
- Plan for execution of the strategy

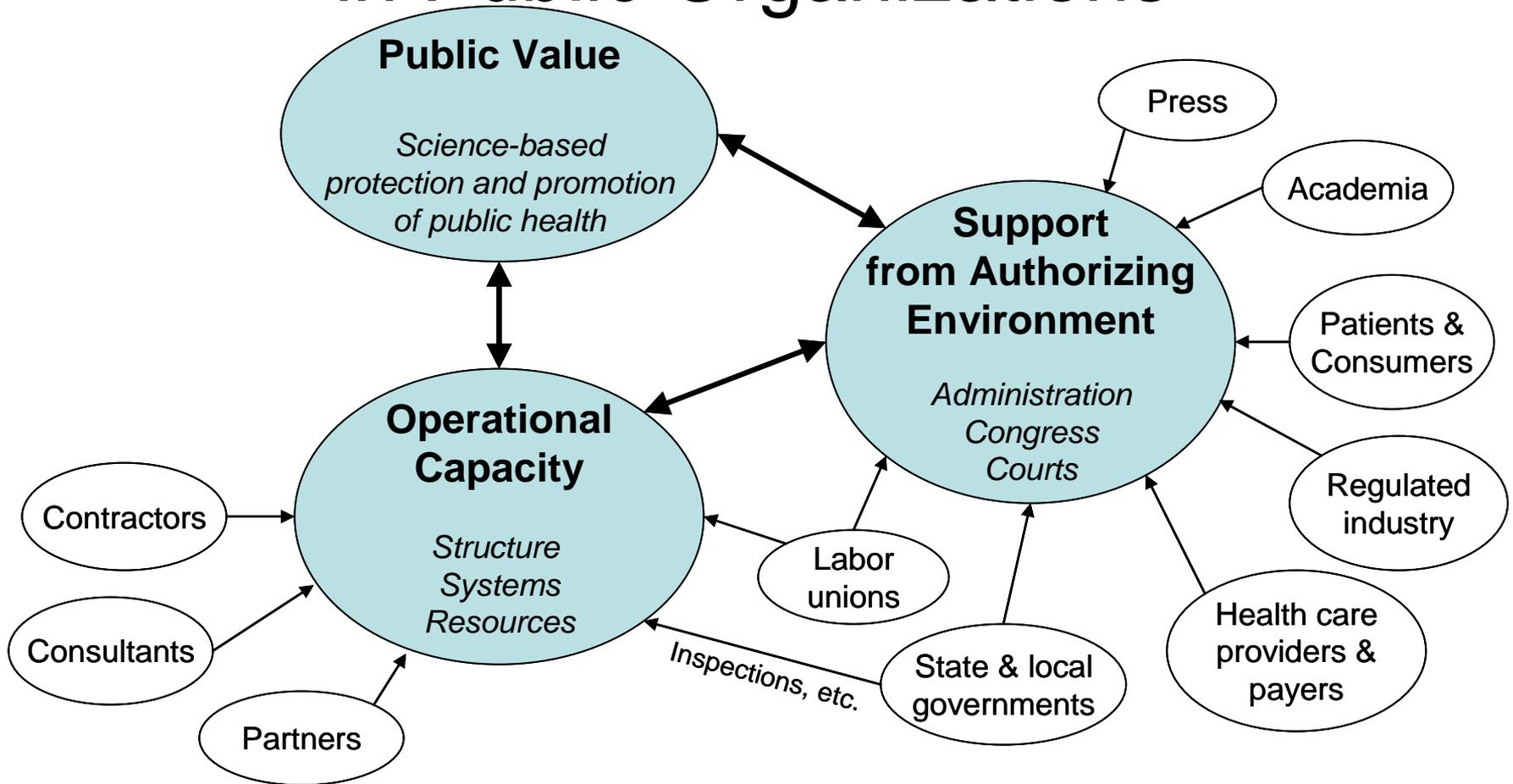


The Strategy Formulation Step



"I THINK YOU SHOULD BE MORE EXPLICIT
HERE IN STEP TWO."

Moore's Model for Strategic Analysis in Public Organizations



Strategic Planning in the Federal Government

- Government Performance and Results Act of 1993 (GPRA)
 - Requires all cabinet-level departments and independent agencies to develop strategic plans
 - Planning horizon covers 6 years (current fiscal year + 5 years out)
 - Updates required every 3 years
 - Also requires annual performance plans and reports
- OMB Circular A-11
 - Sets forth administration guidelines for complying with GPRA and various budget requirements
 - Establishes the annual “Performance Budget”
 - Describes the Program Assessment Rating Tool (PART)

Strategic Planning at FDA

- Alignment with the HHS Strategic Plan Goals:
 1. **Health Care** - Improve the safety, quality, affordability, and accessibility of health care, including behavioral health care and long-term care.
 2. **Public health promotion and protection, disease prevention, and emergency preparedness** - Prevent and control disease, injury, illness, and disability across the lifespan, and protect the public from infectious, occupational, environmental, and terrorist threats.
 3. **Human Services**: Promote the economic and social well-being of individuals, families and communities.
 4. **Scientific Research and Development** – Advance scientific and biomedical research and development related to health and human services

Strategic Planning at FDA

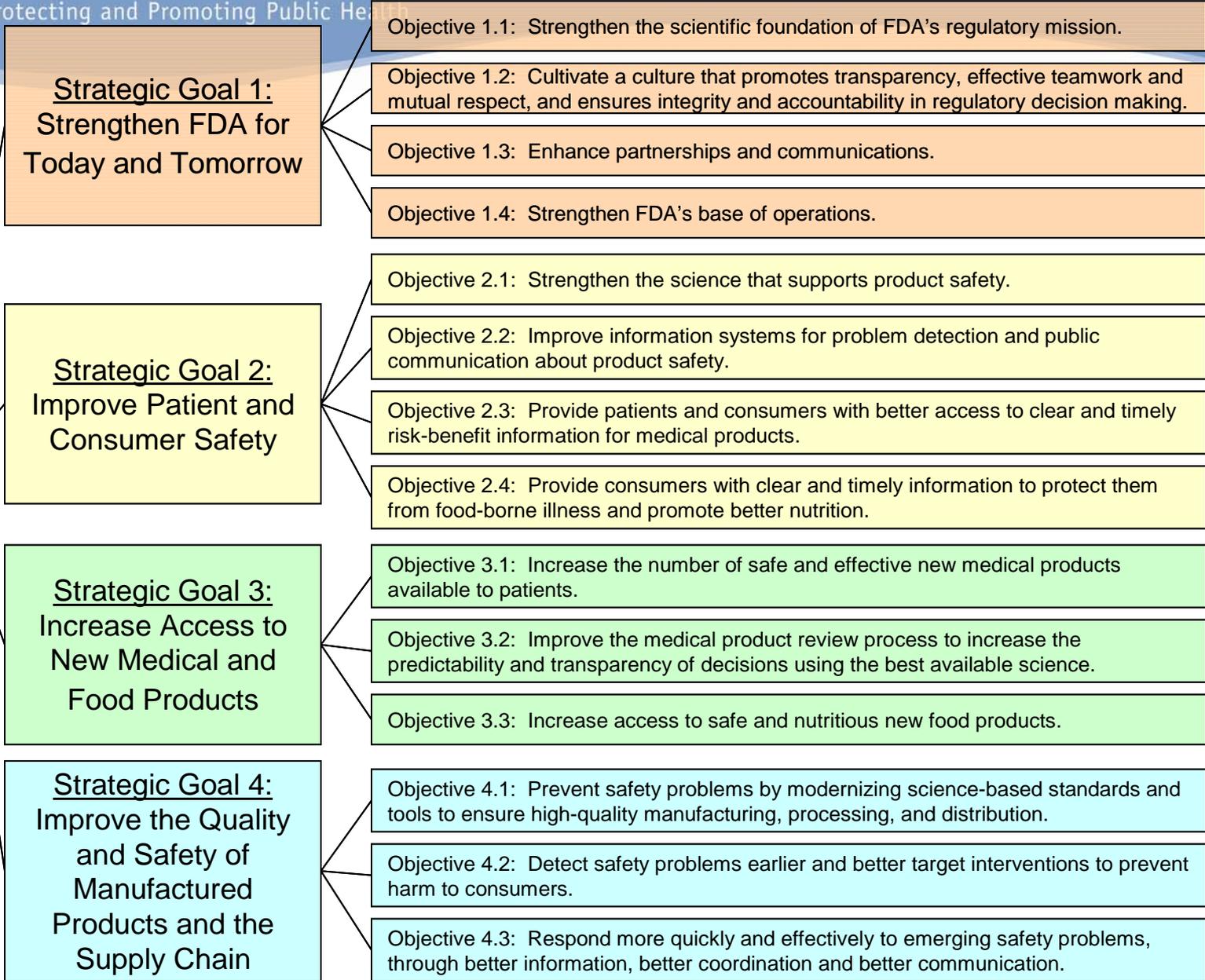
- FDA-wide forums for planning
 - Senior Leadership Team and Management Council
 - Strategic Planning Council
 - Bioinformatics Board
- Center/Office planning
 - Senior Management Team
 - Stakeholder forums

FDA's Strategic Action Plan

- Strategic Goal Framework
 - Four high-level strategic goals based on core mission business processes
- Measures
 - Action item milestones in the plan
 - Annual performance goals align with the plan
 - Moving toward outcome measures for strategic objectives
- Alignment with other FDA plans
 - Center/Office plans
 - IT investments
 - Key initiatives (food protection, import safety, etc.)



**FDA
Mission
& Vision**



Some History Leading to the Risk Communication Strategic Plan

- Institute of Medicine’s “Future of Drug Safety Report” (2006)
 - Recommends FDA sees risk communication as a strategic function and plans accordingly
 - FDA responds by establishing the Risk Communication Advisory Committee (RCAC)
- FDA Amendments Act of 2007
 - Required establishment of the RCAC
- RCAC Recommendation in August 2008
- FY2008 Budget Supplement
 - Commitments include developing and implementing a strategic plan to improve risk communication

Development of the Risk Communication Strategic Plan

- Formulation of a cross-agency working group
- Review and concurrence from several internal FDA committees
 - Strategic Planning Council
 - Communications Council
 - Management Council
- Review by the RCAC
- Integration with agency strategic planning

Risk Communication Strategic Plan Goals

- Strengthen the **science** that supports effective risk communication
- Expand FDA's **capacity** to generate, disseminate and oversee effective risk communication
- Optimize FDA's **policies** on communicating product risks and benefits

Next Steps

- Current RCAC meeting: present strategic plan and research agenda for feedback that will inform revision to final plan due to Congress by end of FY 2009
- Establish some contracts/task orders to contribute to strengthening science
- Work with FDA Centers and Offices, within the overall agency strategic planning process, to develop desired outcomes and action steps to move forward