



# FDA Transparency Initiative

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# Background

- Launched in response to President Obama's Open Government Initiative
- Agency-wide effort to develop recommendations to make useful and understandable information about FDA more readily available to the public
  - Recommendations will be compatible with agency goal of appropriately protecting confidential information

# Transparency Task Force

- Chaired by Principal Deputy Commissioner
- Members consist of FDA senior leadership
  - Center Directors, Associate Commissioner for Regulatory Affairs, Chief Counsel, Chief Scientist
- Work Product: Report to Commissioner Hamburg with recommendations for improving transparency at FDA

# Activities to Date

- Opened public docket
- Launched website and FDA Transparency blog
- Participated in listening session with health care investor community
  - Hosted by White House OSTP

# Activities to Date

- Solicited input from FDA employees
  - Set up internal email address for comments
  - FDA Risk Communication Advisory Committee
- Held public meeting on June 24 to solicit input
  - Over 30 speakers and 125 attendees
  - Over 200 people viewed the live webcast (archived on FDA website)

# Public Interest and Participation

- Significant public interest
  - Federal News Service radio interviews
  - Open Government and Innovations Conference
  - Upcoming FDLI webinar
  
- Hundreds of comments received from a range of stakeholders
  - Consumers, patients, health care professionals, regulated industry, and others

# Reactions to Transparency Initiative

“The Obama Administration is to be highly commended for their righteous efforts in assembling a team at HHS and the FDA who will strive to improve the transparency of our federal agencies to the American public. . . . I applaud your efforts in opening a dialogue with the public to re-build the trust of the American people. Thank you.”

# Reactions to Transparency Initiative

“The FDA is awesome; overall the FDA does a terrific job, but I have a couple of suggestions for improvement. . . .”



# Reactions to Transparency Initiative

“FDA's lost its way and must go back to the original intent to find it. Without that, FDA's been left alone too long pursuing its own goals and now can't find its way home. Who will lead FDA back home? The transparency police? Not likely.”

# Next Steps

- Second public meeting on transparency to be held this fall
- Report to Commissioner Hamburg with draft recommendations

# Sampling of Transparency Topics

- Clinical trials data
- Product applications
- Adverse Event Reports
- Communication tools
- Enforcement actions
- Inspection reports
- Recalls
- Advisory Committee Meetings

# Sampling of Transparency Topics

- FDA Guidance and Rulemaking
- Meeting with stakeholders
- Media Policy
- Consumer Updates
- Safety Information
- Public Meetings
- Approval Process
- Non-approval decisions

# Examples of Transparency Efforts Currently Underway

- FDA's Strategic Plan for Risk Communication
  - Input of Risk Communication Advisory Committee
- Revamp of FDA website
  - Launched this summer
  - Ongoing effort



# Questions?

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