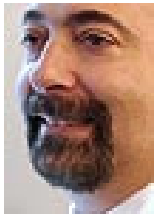
Building a National Framework
Panel 3
Existing and Potential Mechanisms for Promoting Regulatory Science

IOM Drug Forum

February 26, 2010

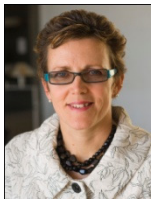
Panelists

Jesse Goodman, MD, MPH
Chief Scientist and Deputy Commissioner for Science and Public Health, FDA



Dale Nordenberg, MD
Novasano Health and Science and Former Assoc. Dir Natl. Ctr. For Infectious Diseases, CDC

Judith Kramer, MD
Executive Director, CTTI & Duke University



Margaret Anderson, MA
Executive Director, FasterCures

Harry Greenberg, MD
Prof and Assoc Dean for Research, Stanford University

Example

- 20 years ago there was a patient at NNMC, Bethesda
- Young(er) FDA funded clin pharm fellow
- Mechanism and prediction of metabolism-based DDI's
- Mechanism and prediction of drug induced cardiac repolarization abnormalities
- FDA and International Guidance
- CERTs research on risk management of known safety issues
- For a brief period of time, FDA was global epicenter of regulatory expertise and research on both these areas

Outline

- Opening comments from panelists
  - What they've heard today
  - Thoughts on Potential Mechanisms for Promoting Regulatory Science
- Facilitated Questions and Answers
- Audience Q&A

Questions to Panelists

- In your view, what is regulatory science and how does it (has it) historically advanced to meet the needs of drug development?
- How important has it been (or should it be) for a regulatory body to have the capabilities to conduct research of regulatory importance?
- How does FDA, industry and academic, if at all, think about the gaps in regulatory science and how are these prioritized and addressed, if at all?
- What are the current mechanism used to address gaps in regulatory science? Current mechanisms used by FDA include: internal research RSR grants, consortia, cooperative agreements/grants, contracts, CRADAs, and use of networks such as the CERTS. Have these been valuable?
- What are the impediments (internally and externally) to have questions raised, prioritized, funded and staffed?
- Reactions to NIH-FDA Initiative?