



Center for Health Transformation
Better Health, Lower Cost

FDA Modernization Project • Advisory Board

Wednesday, June 16, 2010 • 1:30pm – 4:30pm

**Willard InterContinental Hotel • Pierce Room
1401 Pennsylvania Avenue NW • Washington, DC 20004**

1:30pm

Welcome and Introductions

- Overview of CHT FDA Modernization Project
- Purpose of CHT FDA Modernization Project
- Role of Steering Committee
- Role of Advisory Board

Newt Gingrich, Founder, Center for Health Transformation

Andrew C. von Eschenbach, M.D., Senior Director for Strategic Initiatives, Center for Health Transformation

2:15pm

Capacity and Capability: FDA's Challenges in the 21st Century

Andrew C. von Eschenbach, M.D., Senior Director for Strategic Initiatives, Center for Health Transformation

2:30pm

Scope of CHT's FDA Modernization Project

Moderator:

Andrew C. von Eschenbach, M.D., Senior Director for Strategic Initiatives, Center for Health Transformation

Panelists:

Steven Grossman, Deputy Executive Director, Alliance for a Stronger FDA

Fred Hassan, Chairman, Bausch & Lomb and Senior Advisor, Warburg Pincus

Garry Neil, M.D., Corporate Vice President, Corporate Office of Science and Technology (COSAT), Johnson & Johnson

Jay Schnitzer M.D., Ph.D., Associate Chief Medical Officer, Vice President, Boston Scientific

Ellen Sigal Ph.D., Chair and Founder, Friends of Cancer Research

3:45pm

Creation of FDA Modernization Project Working Groups

- Drugs
- Devices
- Food

4:15pm

Overview of Action Items and Next Steps

4:30pm

Adjourn

FDA Modernization Project

A 21st Century FDA is essential to assure personalized, predictive, preemptive, and participatory health.

Vision and Mission:

The **FDA Modernization Project** will develop transformational reforms to food and medical product regulation so that all Americans can enjoy long and healthy lives free from the threat of suffering and premature death from disease.

The Cycle of Discovery-Development-Delivery is the Pathway to a Healthier and Longer Life for All Americans



- **Discovery** of the components of the process and their interactions that determine health and disease must be accompanied by
- **Development** of interventions that are targeted to the critical steps in the process with
- **Delivery** of the right treatment to the right individual for the right reason to achieve the right outcome

The result is the highest quality healthcare for each individual at the lowest possible cost to society.

Personalized Health and Nutrition

(based on understanding of)

Genomics – Proteomics – Metabolomics

(will create innovation in)

Drugs, Biologics, Macro and Micro Nutrients, and Devices

(leading to)

21st Century Integrated Solutions: A New Prescription for Health

The FDA Modernization Project will Develop Strategies which:

- Expands the effectiveness of the FDA workforce
- Enhances the infrastructure especially with new information management systems and modern scientific technologies
- Expedites and streamlines the discovery to development to delivery process
- Enhances patient and product safety including life-cycle and on-going post marketing surveillance
- Incentivizes and incorporates advanced technologies
- Encourages rational, targeted, and mechanistic-based therapies with known outcomes
- Utilizes interventions which are integrated solutions to detect, define, deter or destroy disease
- Integrates regulation of drugs, biologics, macro and micro nutrients, and devices into a holistic framework

The “Three A” Approach to FDA Modernization:

Driving Capacity and Capability to Create a Person-Centric Healthcare System that is:

- **Available:** The FDA regulates the approval of all medical products
- **Affordable:** The FDA impacts the risk and timeline of medical product development and approval
- **Appropriate:** The FDA determines the parameters for the use of medical products in clinical practice

4 Cornerstones of the FDA Modernization Project:

- Communicate the importance of FDA modernization
- Convene the “Best and Brightest”
- Development of Strategies
- Support Implementation of Solutions