2007 ASEAN-U.S. Enhanced Partnership Medical Device Workshop

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Developing a Regulatory System for Medical Devices

July 30, 2007

Presentation Outline

- Principles of Sound Regulation
- Achieving the Right Balance
- Understanding Stakeholder Needs
- Achieving Regulatory Flexibility
- Connecting the Dots

Principles of Sound Regulation

- Establish Clear Objectives
- Understand the Needs of All Stakeholders
- Create a Regulatory System to Meet Goals
- Develop and Communicate Expectations to All Stakeholders

Achieving the Right Balance

Public Health Protection

vs.

Availability of Products

Absolute Safety and Effectiveness

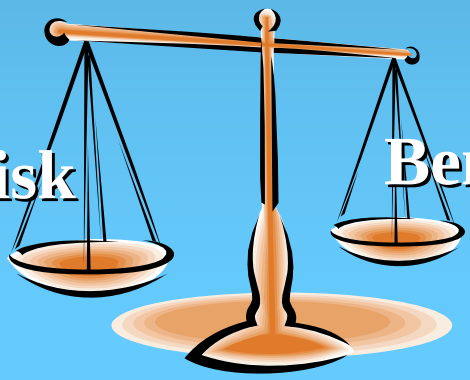
vs.

Reasonable Assurance of Safety and Effectiveness

Risk

vs.

Benefit



Guiding Principles for Achieving the Right Balance

Regulatory Decision Making

- Based on Sound Science and the Law

Addressing Regulatory Issues

- One Size does not fit all
- Alternative approaches

Understanding Stakeholder Needs

- Patients
- Healthcare Providers
- Regulated Industry

Why is Regulatory Flexibility Needed?

- Scope of Medical Devices
- New Technology Presents Challenges
- New Technology Someday Becomes Old Technology

Achieving Regulatory Flexibility

- The "Value Added" Proposition
- Efficient Reclassification Mechanisms
- Considerations of Available Data Sources

Achieving Regulatory Flexibility

Combination Products

- Cutting Edge Technology Combining Drugs/Devices/Biologics
- Regulatory and Policy Challenges
- Ensuring Timely Patient Access

Connecting the Dots

A Systems Approach to Regulation