Summary Recommendations to FDA

Society of Thoracic Surgeons' Perspective

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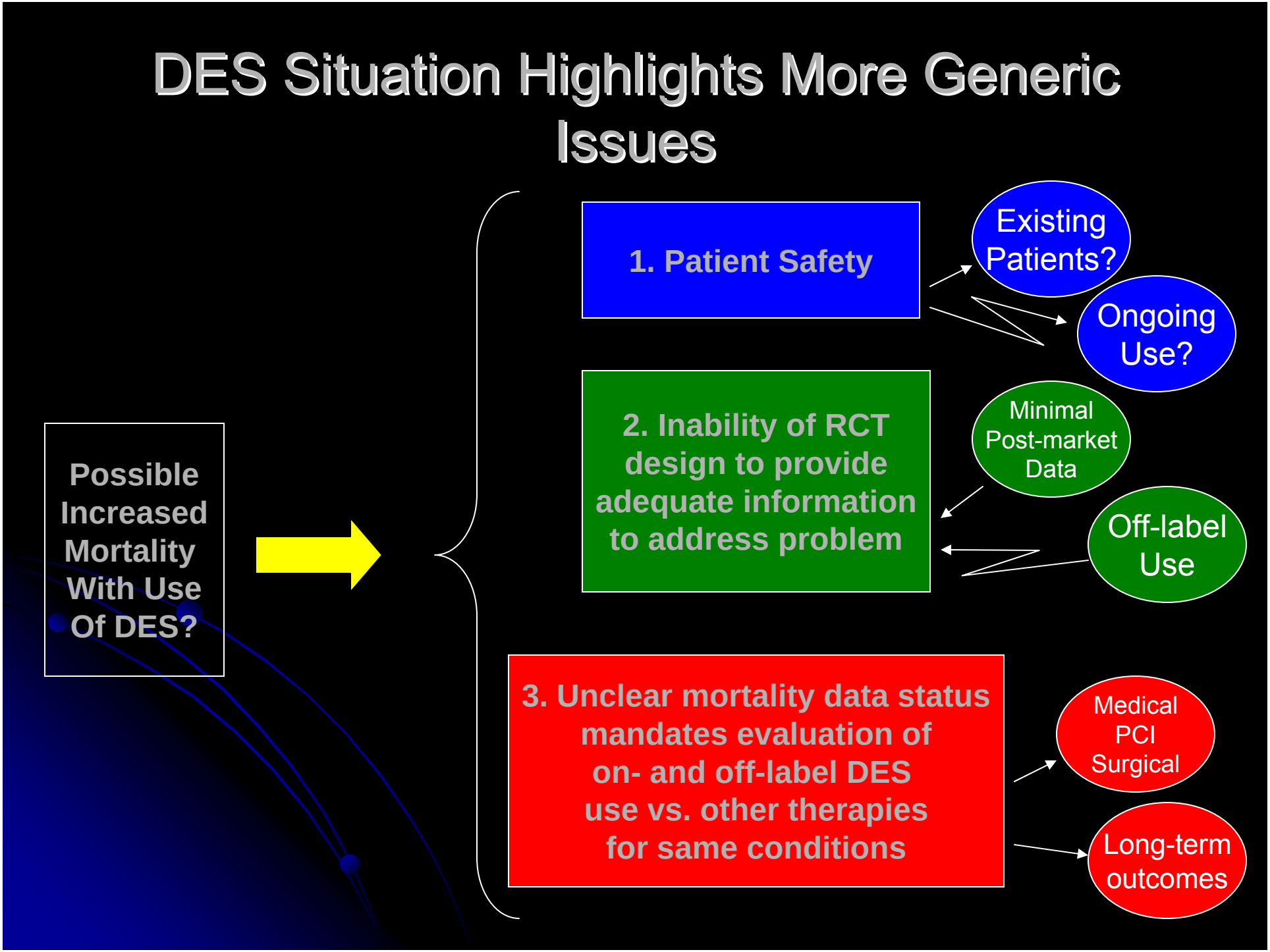
Disclosure

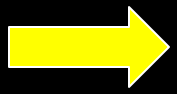
- The speaker has no financial involvement with the products being discussed in this presentation or this meeting.
- The Society of Thoracic Surgeons has paid for travel and lodging expenses for the speaker to attend this meeting.

DES Situation Highlights More Generic Issues



Consequence #1

Possible Increased Mortality With Use Of DES?



Impact On Patient Safety

- ***Uncertainties*** about:
  - Patient management
    - Therapy selection?
    - Plavix™ use and discontinuation?
  - Focus of Treatment
    - To what degree is there a patient-centric focus in current PCI practice?
  - How data will address this issue
    - RCTs vs. “Registries?”
  - Patient communication
    - What are the drivers for current communication?
    - What are therapeutic risks, benefits are currently being discussed?

STS Recommendation # 1:

- Informed Consent Communication that is ***Accurate and Complete*** is essential for **Patient Safety**:
  - A ***patient-centric*** focus of communication (IOM, 2006)
  - Full and complete disclosure of risks and benefits should take place after diagnosis but BEFORE intervention
  - Information disclosed should include ALL available objective data, including long-term data, not just RCT data
  - This patient-centric communication is ideally conducted by a ***multi-disciplinary team approach*** when there are multiple therapeutic options with presumed clinical equipoise (i.e., medical Rx, PCI, & CABG) for underlying medical condition (i.e., multi-vessel CAD)

Consequence # 2

Potential Increased Mortality With Use Of DES?

Liability of Incomplete Information

- life cycle of potentially effective therapies ≤ validation cycle for RCTs
- expansion of indications beyond RCTs compounds this information liability, and therefore increases patient-level risk
  - FDA Labeling is based on pivotal RCTs of single vessel stenting; implications for MVD ?
- highlights need for new, more complete information:
  - contemporaneous “real world” technology use data
  - observational populations representative of clinical practice to more completely assess medical and financial effectiveness of therapies

CDRH's Postmarket Transformation Leadership Team Report

- **FDA 9 November Announcement:** FDA Initiative #3: Enhanced Risk / Benefit Communication Efforts
  - "Maximize the FDA's ability to communicate information clearly and quickly to practitioners, patients and consumers"

- **Is there an opportunity to share clinical information between specialty societies and the FDA?**

Information Collaboration Opportunity: Example

- Medicare/FDA evaluation of Trans-Myocardial Laser Revascularization (TMR)
  - STS Database used for industry-funded Postmarket analysis → combined CABG+TMR; study outcomes raised concerns ***(Peterson et al, JACC 2003; 42:1161-6)***
  - STS Database data → key in MCAC analysis of "real-world" data → confirmed effectiveness
  - Medicare recognized follow-up through STS Database mechanism as important and useful

FDA-Society Information Collaboration

- Potential Advantages:
  - Major observational Database systems already in place *(STS Database > 3 M records, > 750 sites)*
  - Established collaboration with multiple State Database/Reporting Systems (MA, CA, NJ).
  - Track record of robust scientific analyses
  - Databases have been the basis of Society-led QI efforts, and now for P4P and public reporting
  - Representative of “real world” clinical practice
  - Greater degree of objectivity and scientific integrity than “Registries” sponsored by device companies

STS Recommendation # 2

- FDA, as part of their Postmarket Transformation, should develop data partnerships with Professional Society-led Databases to provide data on important new technologies where available
- FDA should influence and engage technology companies in the support of these follow-up efforts

Consequence # 3

Absolute Excess Mortality With Stent Therapy vs. CABG in MVD (> 3600 deaths /yr)

Unacknowledged Lack of of Clinical Equipoise

- At ***patient-centric*** level, survival advantage is being withheld
- At ***FDA and Medicare level***, ability to assess effectiveness of new technology limited until all aspects of equipoise (i.e., long-term outcomes data) can ultimately be evaluated
- now established as clearly important in multi-vessel CAD therapy

FDA-Professional Society Partnerships

- **Partnerships would strengthen the Postmarket Transformation Program as follows:**
  - Quality of information will in part be based on the "consistency of use" of new technology in everyday clinical practice
  - A multi-disciplinary informed consent process would also positively influence this use consistency
- **Challenges:**
  - Long-term followup data will be necessary to evaluate new therapies with clinical equipoise to existing therapies
  - Funding
    - Provider-led Databases supported by providers
  - Long-term patient follow-up mechanisms
    - Current HIPAA and other regulations make long-term patient follow-up difficult

STS Recommendation # 3

- Active, Robust Comprehensive Databases should be developed through Partnerships between the FDA and Professional Societies as part of the Transformation Program
- In these Partnerships, the FDA can influence funding and regulatory issues for the Societies, and the Societies can influence adoption and consistency of use of the new technologies for the FDA
- The excess mortality in MVD with PCI vs. CABG mandates that in the FDA Labeling, MVD should be included in the patient subsets in whom the safety and effectiveness of stenting has not been established.

Summary

- #1: A multi-disciplinary, patient-centric disclosure prior to intervention will optimize patient safety surrounding new technology introduction and adoption
- #2: The FDA should explore information collaboration opportunities with Society-led databases where they exist
- #3: Active, robust comprehensive databases should be the basis of Partnerships between the FDA and Professional Societies to assist the FDA in evaluation of patient safety and clinical benefit issues surrounding new technology adoption into clinical practice