Statement of the American College of Cardiology to the Circulatory System Devices Panel of the FDA Medical Devices Advisory Committee

David R. Holmes, Jr., MD, FACC
President

July 20, 2011
Disclosures

• No conflicts to disclose
The Mission of the ACC

To advocate for quality cardiovascular care – through education, research promotion, development and application of standards and guidelines – and to influence health care policy.
We represent…

- 40,000+ members (>90 percent of U.S. cardiologists)
- 7,000 manuscripts submitted
- 20,000 live-event attendees
- 40,000 CME recipients
- 11 million patient records in NCDR®
- 100 million patient visits
ACC Goals for TAVR

• High quality patient care
• Efficient and appropriate access to new technology
• Ensure appropriate patient selection for and the safe application of this technology
• Rapid response to continued evolution of new technology (specifically device iterations)
• Development of new scientific studies and approaches for specific diseases
• Cooperation among all involved
TAVR collaboration

• Primary stakeholders
  – Physicians
  – Government
  – Industry
  – Patients

• Within physician community
  – Primary cardiologists
  – Interventional cardiologists
  – Surgeons

• Multiple professional societies

Common goal: High quality patient care
Clinical documents in development

- Societal Overview of TVT by ACCF and STS (July 2011)
- SCAI-led competence statement addressing institutional and operator requirements (early 2012)
- ACCF-led expert consensus document on pre- and post-procedural issues, including patient selection (early 2012)
- ACCF-led update of structural heart disease guideline (TBD)

All multi-societal efforts involving physician stakeholders
Planning for Success

- Multi-disciplinary heart team
- Patient selection:
  - Right patient
  - Right place
  - Right time
- Facility requirements
- Operator experience
- Post-market surveillance
Multi-disciplinary heart team

• Primary cardiologist
• Interventional cardiologist
• Cardiothoracic surgeon
• Echocardiographer
• Cardiac imaging specialists
• Heart failure experts
• Other clinical and paramedical team members
Facility requirements

• Multidisciplinary heart team
• Structural heart disease experience
• Participation in national clinical databases (ACC NCDR®/STS)
• Must be able to accommodate catheterization equipment and surgical equipment
• Two options:
  – Modified catheterization laboratory
  – Hybrid operating suite
Operator training and education

• Medical specialty societies conduct education on:
  – Patient selection
  – Disease state: pathophysiology, expected outcomes
  – Treatment options: selection and timing
• Industry conducts device-specific site and operator training
• Joint training and team training: ACC and STS have developed joint educational programs for TAVR
Post-market surveillance: Goals

- The numerator and denominator of patients receiving a device are both crucial.
- Primary goals are the assessment of effectiveness and safety when applied in clinical practice for ALL patients who receive the device, not a subset.
- Use existing infrastructure of national clinical data repositories to capture ALL patients undergoing device placement: ACC/NCDR and STS
Post-market surveillance: What is involved

• Infrastructure, well-designed data forms to allow seamless collection of data for:
  – New iterations of the device(s)
  – New adjunctive strategies (embolic protection, etc.)
  – Changes in approach (transapical, subclavian, transfemoral)
  – Changes in patient selection criteria and outcome over time
Clinical data repositories

• Patient safety
• Device/therapeutic effectiveness
  – Specific devices/therapies
  – Comparative effectiveness
• Quality improvement
• Compliance
Clinical data repositories: What do we have?

• Existing national clinical databases
  – ACCF NCDR®
  – STS

• Leverage scientific and clinical expertise and harmonize:
  – NCDR®
  – STS Adult Cardiac Surgery Database
  – CMS MEDPAR database (Medicare Provider Analysis and Review)
Benefits

• Leverage existing relationships between physicians/hospitals and clinical data repositories
• Data collection and data standards infrastructures already exist
• National registry of therapies for structural heart disease
  – Comparative effectiveness research
  – Cost effectiveness research
The bottom line

Provide expert care by expert teams in expert centers for carefully selected patients to optimize the results obtained with this transformational technology called TAVR