Cardiac Safety: Where Are We? Where Do We Need To Go?

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Why Have We Joined Together

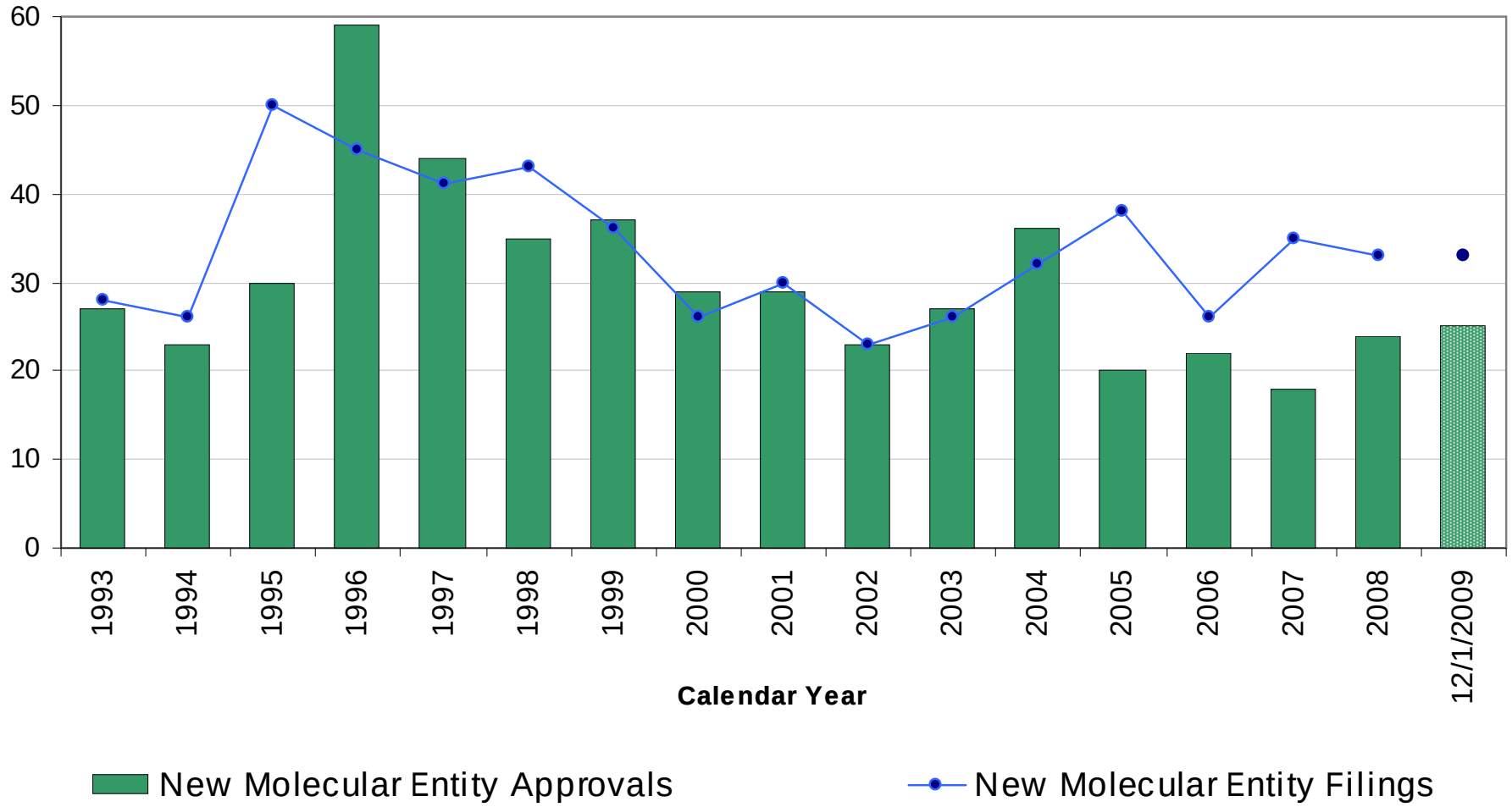
- Because We Have To

Pressures on Medical Product Development and Use

- Societal expectations higher than ever:
  - Faster development of needed therapeutics
  - Safer and more effective therapies
  - More information with less uncertainty sooner….
  - Comparative safety and effectiveness
- Perception that society (and regulators?) have become risk-averse
- Medical Product development is not keeping pace with these expectations

Challenge of Safety

CDER NME Filings and Approvals



Source: CDER Data as of 12-1-2009

Reinvigorating Efficient Product Development

- The old approach is not working
- Change requires collaboration to capitalize on the expertise and resources of multiple groups (PhRMA, FDA, CSRC, Societies….)

Where Are We?

Consortia Can Successfully Address Scientific Challenges & Reinvigorate Product Development

Characteristics of Success Consortia

- Broad involvement of affected parties
- Transparent
- Science-Driven
- Work matters for public health impact

Example of Successful Consortium

CAMD

- Coalition Against Major Diseases
- Focus on Parkinson's and Alzheimer's
- Collaboration: C-Path, Brookings Institute, Academic and Industry
- Accomplishments:
  - Alzheimer's Disease Model
  - Placebo control database from 11 trials
  - Proposals for cognitive assessment scale and imaging standards

Where Do We Need To Go?

Focus on High-Impact Areas

Integrate Non-Clinical and Clinical Data

Example: CV Consortia/ CSRC

ECG Data Warehouse

- Collaboration to build a repository of more >4 millic ECGs in a single electronic data warehouse
- Accomplishments
  - 25,000 records from TQT studies (Moxi/Placebo) made public

HESI-CSRC Collaboration

- Pre-clinical cardiac safety

Other Work….

Example: Patient Reported Outcomes (PRO) Consortium

- Focus on development, evaluation and qualification of PRO instruments for use in clinical trials
- Partners: Industry (n=25), Government (inc EMA), Academics
- Impact across many therapeutic areas
  - Areas historically difficult for drug development

PRO Consortium Work to Date

- Identified 33 indications that are sx-based
- Identified top 8 areas where PROs are needed, inc:
  - Asthma
  - Depression
  - IBS (Irritable Bowel Syndrome)
  - Pain
  - Cognition
  - Fatigue
- Scoping documents for Asthma, Cystic Fibrosis, Depression, and Non-Small Cell Lung Cancer created

Summary

- Why share? Why CSRC?
  - We all have a shared goal of reinvigorating efficient medical product development to deliver on the promise of the new science
    - Expectations on healthcare continue to increase
  - Have to work together to succeed
- Successful consortia can and are making a difference
  - CSRC is a productive model
- Current environment requires renewed attention to assure productivity