Greetings & Opening Remarks

Alberto Gutierrez, Ph.D.

Thank you

- Organizers
  - Sheri Hall
  - Jean Cooper
  - Sayah Nedjar
  - Lisa Brown
- AMDM
- Hogan Lovells
- Presenters

IVD Roundtable

- Long History
- Improve Communication
- Initial meetings resulted in tangible Work Products

CDRH Initiatives and Changes

- Continuing Program review – 510(k)
  - Internal Review
    - Proposals published on August 3, 2010
  - IOM Review
    - Expected in 2011
- Organizational Changes
  - New Center Deputies

Hype vs Reality

- “FDA proposes stricter rules on approving medical devices” Chicago Tribune
- “Bad Times Ahead For Pharmaceutical Innovation” Forbes
- “New appointment of FDA official unsettles medical device industry” MedCity

IVD Initiatives and Directions

Dr. Gutierrez, upon taking the OIVD Director's position in July 2009, expressed numerous regulatory pathway concerns:

- "flaws in the 510(k) premarket notification program in that "substantial equivalence" allows a test maker to show its test is similar to an already cleared device in lieu of a more extensive safety and efficacy review
- A process that "invites unwanted variability among test makers
- Use of labeling terms, such as "sensitivity" (rate of true positives) and "specificity" (rate of true negatives) even when the terms "don't really describe what manufacturers actually proved to us."