

January 24, 2010

About CLSI

John Rex, MD
Chair, Area Committee on Microbiology

My Disclosures

- John H. Rex, MD
 - Vice President Clinical Infection, AstraZeneca Pharmaceuticals
- Other relevant background
 - Professor of Medicine, University of Texas Medical School-Houston
 - Member (1993-2002), Chair (2003-08), and Advisor (2009-present) Antifungal Susceptibility Testing Subcommittee (AFST)
 - Chair, CLSI Area Committee on Microbiology (2009-present)

CLSI Background

- CLSI is:
 - A non-profit organization
 - IRS 501c3 (educational mission)
 - Founded 41 years ago as NCCLS
 - An accredited standards development organization
 - American National Standards Institute (ANSI)
 - Closely linked to the International Organization for Standardization (ISO)

CLSI & ISO

- International Organization for Standardization (ISO) is
 - The world's largest developer of international standards
 - A network of the national standards institutes of 162 countries, one member per country
- CLSI is the Executive Secretariat for
 - The ISO Committee for the Clinical Laboratory
 - The ISO Subcommittee on Anti-microbial Susceptibility Testing
- CLSI's antibacterial MIC method & QC values
 - Are the basis of 2 ISO standards

CLSI & WHO

- World Health Organization (WHO)
 - The directing and coordinating authority for health within the United Nations system
 - Responsible for providing leadership on global health matters, **setting norms and standards**, and providing technical support to countries and monitoring and assessing health trends
- CLSI is
 - The only WHO-designated collaborating center for clinical laboratory standards in the world

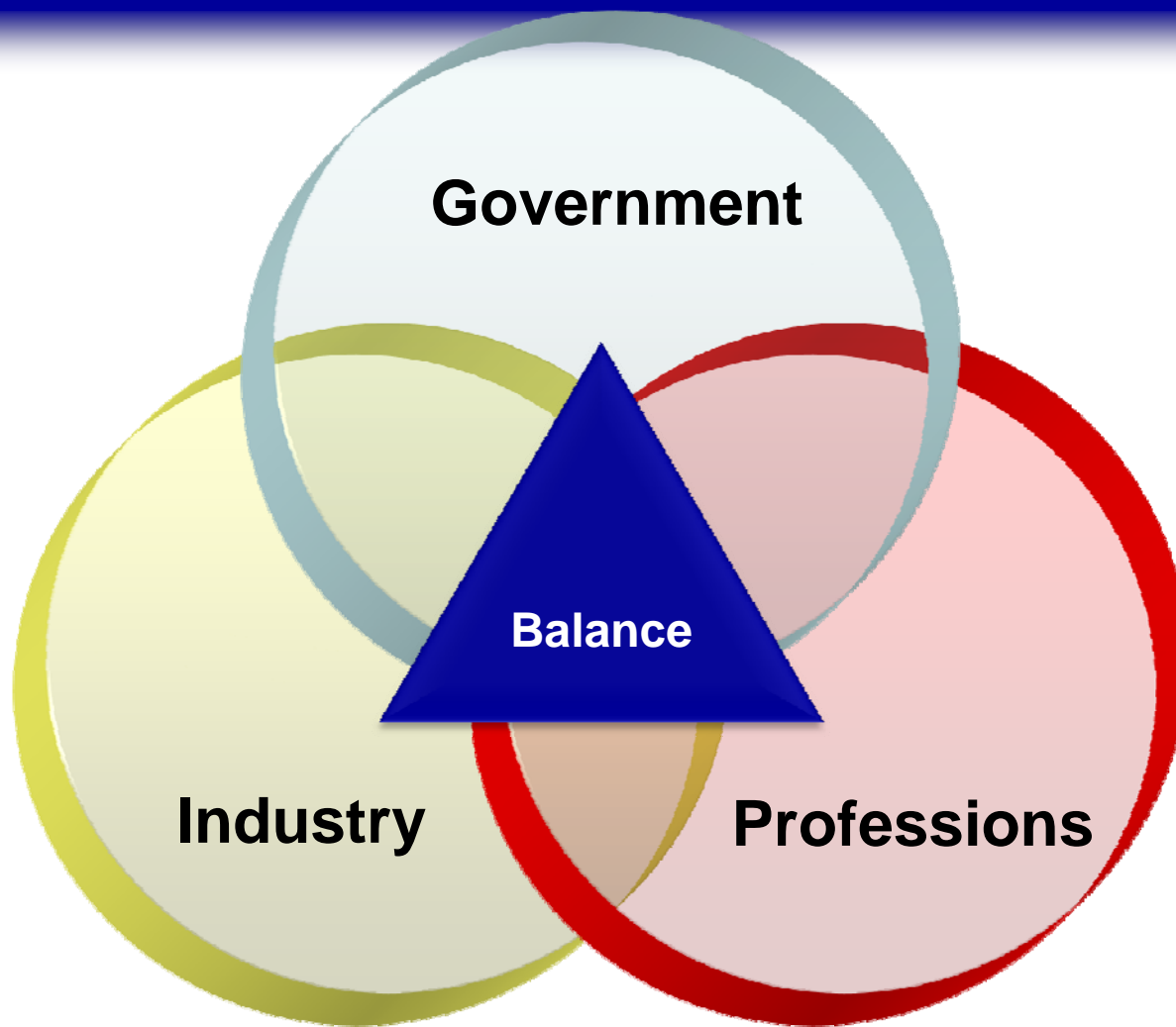
CLSI's Member Organizations

- Public & Private Labs, Industry & Government
 - 1,600 hospitals and laboratories
 - 130 industry organizations
 - 40 government agencies
 - 40 startup companies & consultants
- Institutions & Societies
 - 70 educational institutions
 - 35 professional societies
- Member organizations represent 70+ countries

Volunteers

- > 2,000 volunteers write CLSI's library of >200 standards & guidelines
- >75 active projects ongoing at any given time
- Volunteers are scientific thought leaders and well respected in their field
 - Most hold a PhD or an MD
- CLSI volunteers have global reach
 - Approximately 30% reside outside North America

CLSI Consensus Process





CLSI's Consensus Process

- Fully Open Process: Meetings available to all
- Transparent: Materials are fully available
- Inclusive: Industry, Academia & Government
- Balance of Interests
- Conflict of Interests Fully Disclosed
- Appeals Process

CLSI & Antimicrobial Susceptibility Testing (AST)

- CLSI has been the World Leader for 30+ years in:
 - Establishing the Methods for AST Testing
 - Establishing Quality Control ranges
 - Establishing & maintaining updated Interpretive Breakpoints
- The CLSI AST Committees are
 - Comprised of world-renowned experts
 - Includes representatives from Academic, Infectious Disease, Regulatory and Public health agencies, EUCAST and EMEA, etc.

CLSI & Antimicrobial Susceptibility Testing (AST)

- ANSI has approved CLSI's AST standards as US National Standards
- National lab accrediting bodies (CLIA...CAP) require methods consistent with CLSI standards
- CLSI methods and interpretive criteria are used in almost every US clinical microbiology laboratory
- CLSI AST standards are de facto national standards in over 50 countries, and translated into six languages

CLSI & Antimicrobial Susceptibility Testing (AST)

- For over 2 decades, CLSI AST interpretive criteria have been embedded in the software of the FDA-cleared devices producing >85% of all microbial identifications and susceptibility testing results.
- FDA-approved drug labels reference CLSI/NCCLS testing methods and QC measures as being the relevant national standards
- FDA CDRH requires that CLSI methods be used as the reference procedures to which any new device is compared for FDA clearance

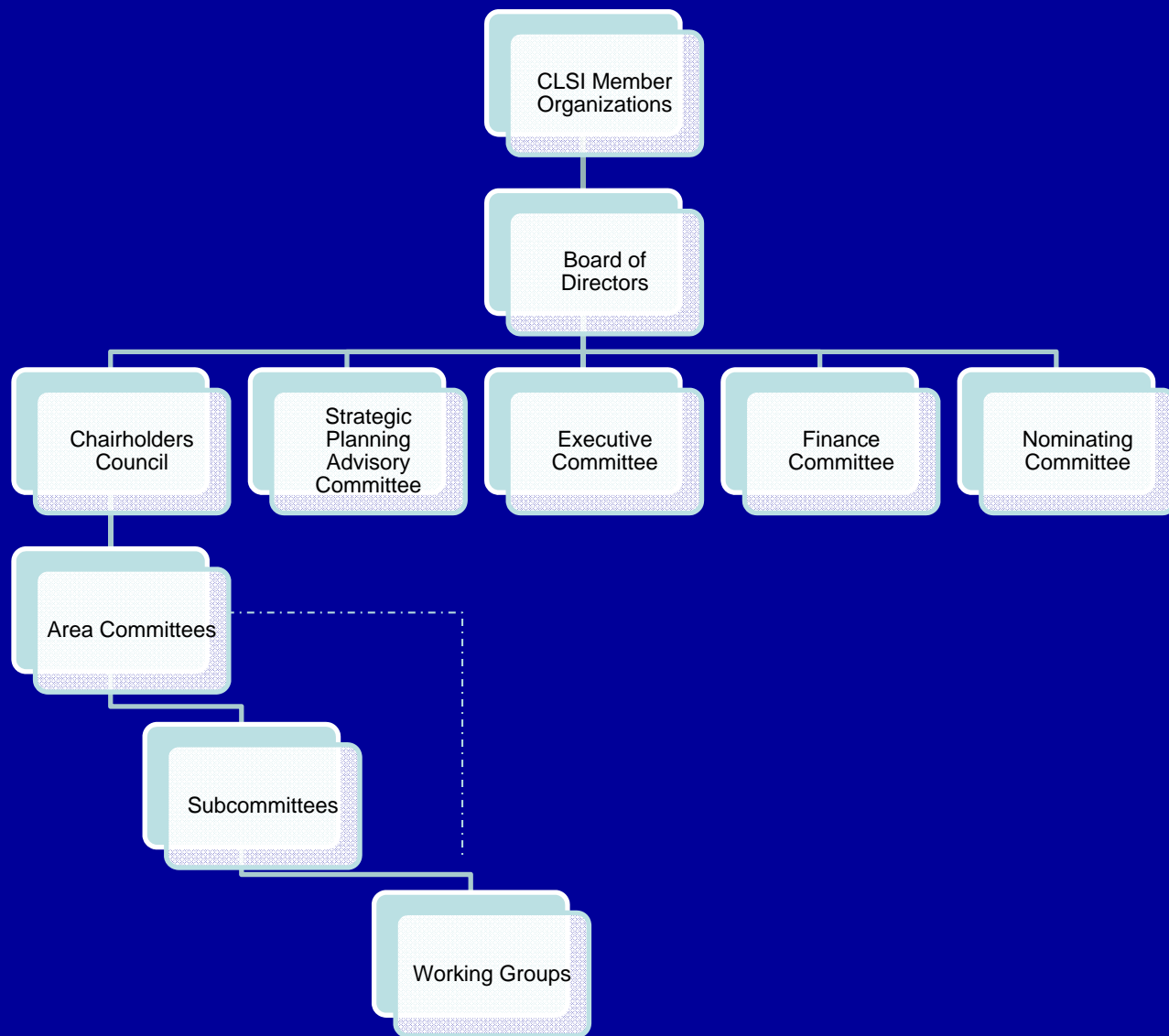
CLSI & Antimicrobial Susceptibility Testing (AST)

- CLSI's Microbiology Standard Methods include
 - M23: Developing Interpretive Criteria & QC parameters
 - M2 & M7: Broth & agar-based testing of aerobic bacteria
 - M11: Testing of anaerobic bacteria
 - ... and 32 others
- These method documents are updated regularly
 - Semiannual face-to-face meetings
 - Teleconferences
 - Subcommittees and Working groups
- All material & processes are open for review

How it all works



Organizational Structure





CLSI Area Committees

- Automation and Informatics
- Clinical Chemistry and Toxicology
- Evaluation Protocols
- Hematology
- Immunology and Ligand Assay
- Microbiology
- Molecular Methods
- Point-of-Care Testing
- Quality Systems and Laboratory Practices

2010 Area Committee on Microbiology

- Professions

- Betz A. Forbes, PhD, D (ABMM) – Medical College of Virginia
- Thomas R. Fritsche, MD, PhD – Marshfield Clinic
- Mary Jane Ferraro, PhD, MPH, **Vice-Chairholder**

- Industry

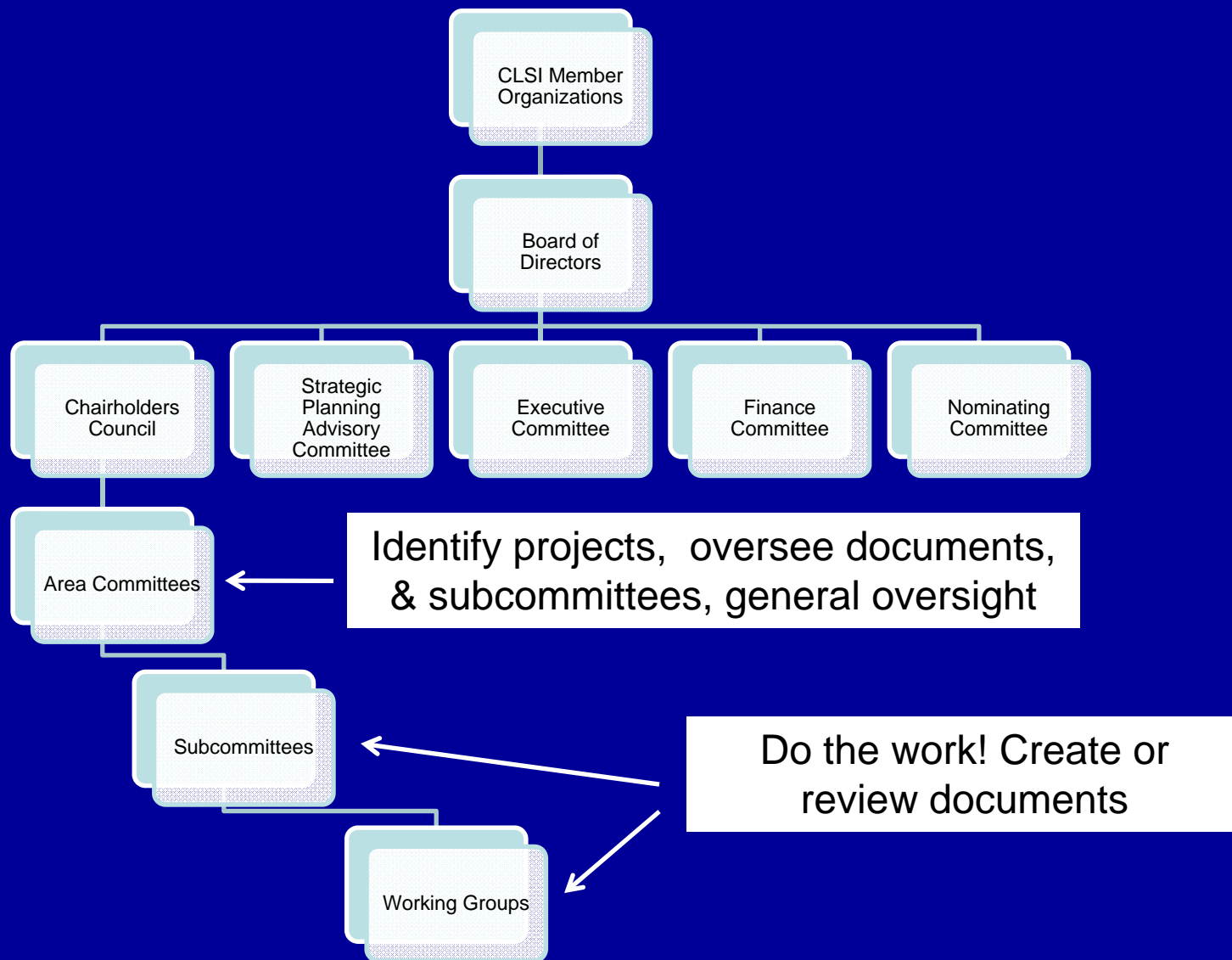
- John H. Rex, MD, FACP, **Chairholder**
- Barbara Ann Body, PhD, D (ABMM) – Laboratory Corp. of America
- Fred C. Tenover, PhD, ABMM - Cepheid

- Government

- Nancy L. Anderson MMSc, MT (ASCP) – CDC
- Freddie Mae Poole – FDA Ctr. For Devices/Rad. Health
- John D. Turnidge, MD – Women's and Children's Hospital

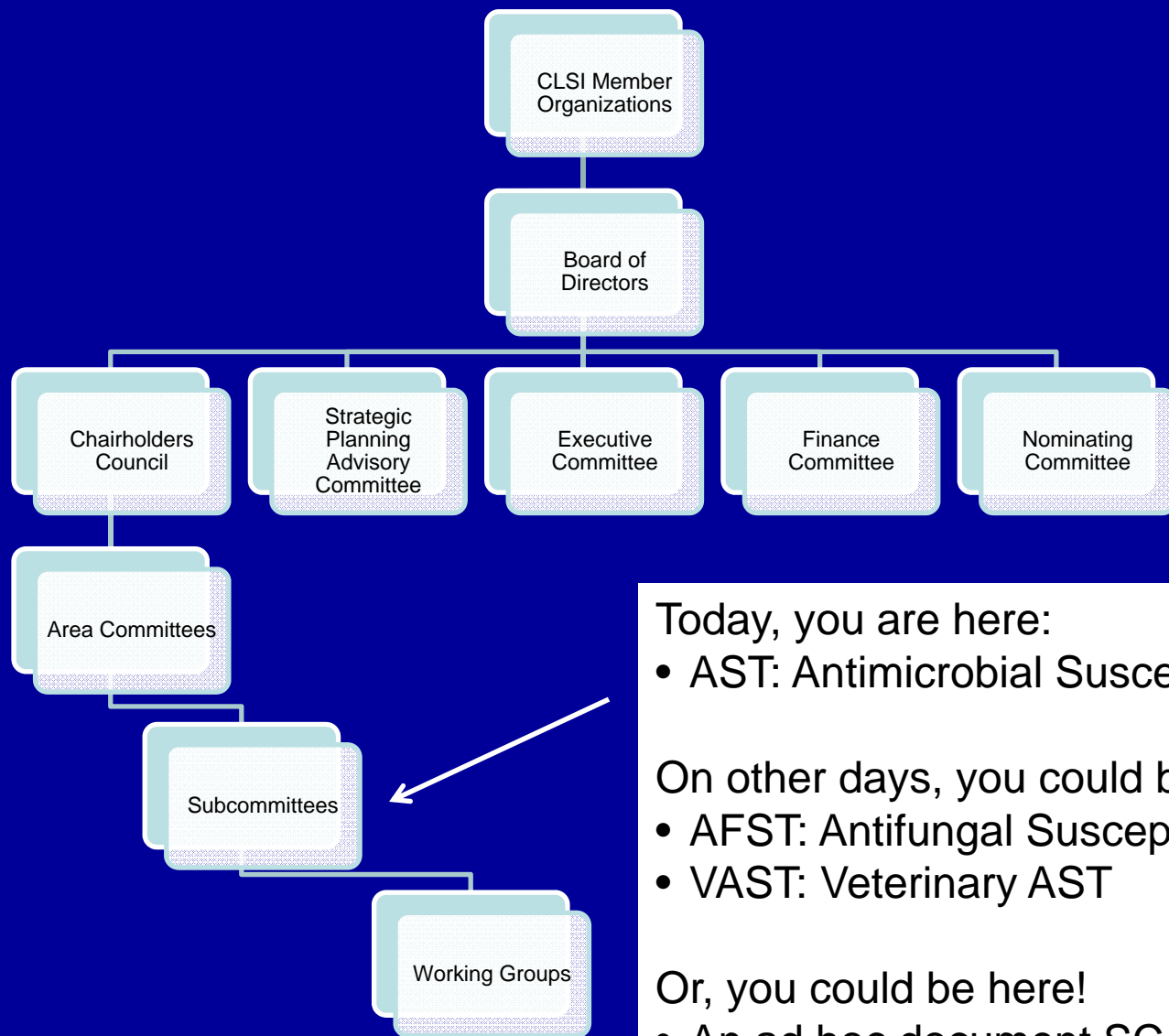


Organizational Structure





Organizational Structure



Today, you are here:

- AST: Antimicrobial Suscept Cmte

On other days, you could be in ...

- AFST: Antifungal Suscept Cmte
- VAST: Veterinary AST

Or, you could be here!

- An ad hoc document SC
- A working group

Area Committee Chair & Vice-Chair

- What Mary Jane and I don't do
 - We are not members of any SC
 - We do not have a vote on any SC
- What we do
 - Chair the Area Committee
 - Propose new documents & revisions of old documents
 - Focus on process for the entire Microbiology Area
 - Connect the Microbiology Area to the other Areas

So, on to my specific comments

Three themes

- Thank you all for contributing your time!
- Process & Disclosures
- Documentation
- I now have two additional presentations for you
 - The Area Committee report: This is on your disk
 - AC Membership, active subcommittees & reports
 - I am not going to spend time on it today
 - A review of some relevant events in the United States