



# Oversight of Genetic Testing

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# History of Government Oversight of Genetic Testing

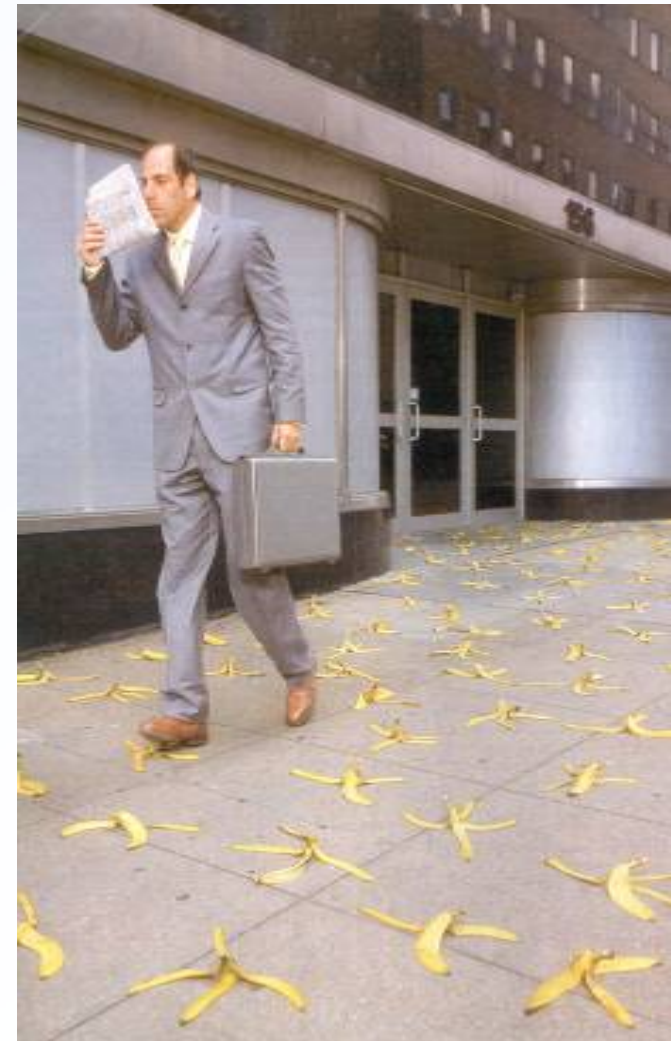
- 1993 - NYS Task Force on Life and Law Committee
- 1997 - NIH/DOE Task Force on Genetic Testing
- 1997 - CLIAC Genetics Subcommittee
- 1998 - Secretary's Advisory Committee on Genetic Testing (SACGT) chartered
- 2000 - CDC's Notice of Intent on Genetic Testing Specialty
- 2003 - Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS)
- 2006 - CMS halts Genetic Testing specialty under CLIA
- 2007 - SACGHS Task Force on Oversight



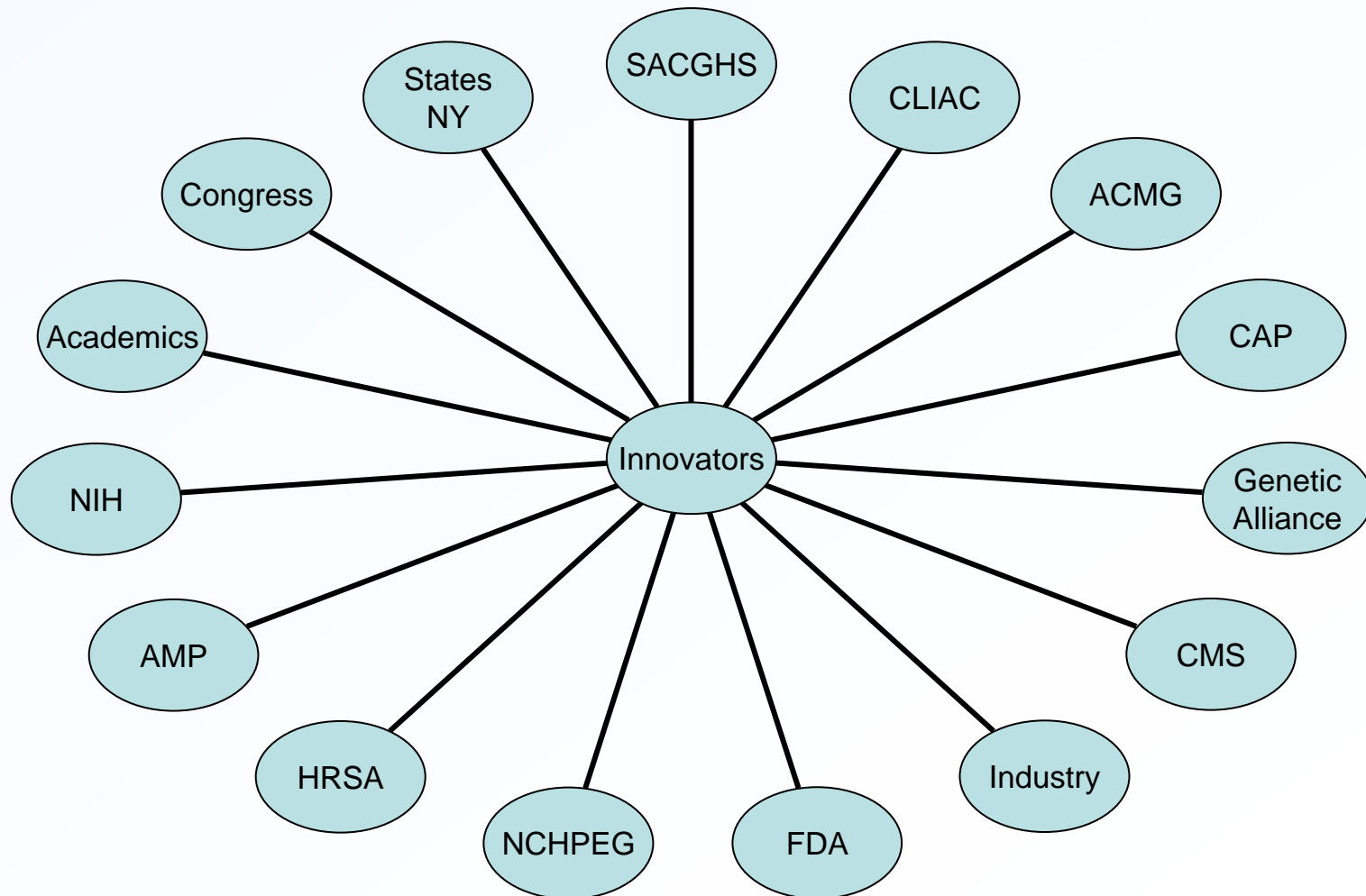
# Oversight of Genetic Testing

## Reasons behind some US issues

- Laboratory practice vs Medical practice
- Minimal requirements vs ideal
  - ❖ Analytical validity - CLIA
  - ❖ Clinical validity – Who?
  - ❖ Laboratory developed tests
- Concern about new applications
  - ❖ Internet (Tests to Public)
  - ❖ Testing moving out of academic centers
  - ❖ Technology driven
  - ❖ New social issues
  - ❖ Poor knowledge base – public and clinicians
- Growth of patient advocacy
- Promise - personalized medicine
- Balancing access and quality



# Some of the key US players





# Some Key International Players

- Organization for Economic Cooperation and Development (OECD)
- UK NHS
- EuroGentest
- International Organization for Standardization (ISO) – Standards 10725 and 15189
- International Laboratory Accreditation Cooperation (ILAC) – Guidelines ILAC–G13

## Some important questions to ask

- Is the current level of oversight being provided adequate and if not what needs to be changed?
- Does genetic testing require a completely different oversight process from that being used for other types of laboratory tests?
- Are all the mechanisms that could be used to achieve oversight – regulatory, voluntary, incentive-based – being appropriately engaged?
- Can an oversight framework be developed that is agile enough to address a rapidly moving field and assure appropriateness and effectiveness?





# Oversight of Genetic Testing

## Oversight of Genetic Testing: SACGHS Task Force

- Dr. Andrea Ferreira-Gonzalez – University VA

## OECD Guidance- QA for Molecular Genetic Testing

- Dr. Ira Lubin - CDC

## Genetic Testing – FDA’s Regulatory Perspective

- Drs. Alberto Gutierrez and Elliot Cowan

## Plans for MMWR and Genetics Consortium

- Dr. Bin Chen



**Thank you**  
**Questions/Comments**