Genetic Testing Oversight: 2008 SACGHS Report on GT Oversight

Phyllis Frosst Ph.D.
Acting Chief, Policy and Program Analysis Branch
National Human Genome Research Institute

June 05, 2008
House of Lords Inquiry on Genomic Medicine Visit

How do we move towards policy consensus and implementation?

Generally by Committee

The Secretary's Advisory Committee on Genetics, Health and Society

- Respond to extraordinary scientific advances
- Maximize benefit to health
- Provide a forum for genetic/genomic issues
- Assist DHHS at their request
- Make recommendations to the Secretary

- 17 Members, 19 Federal Representatives
- Wide range of stakeholders

Secretary's Request

Identify gaps in the US system of oversight of genetic testing, and make recommendations regarding how those gaps might be filled.

The Process

- Very tight timeline
- Task force of ~30 people
- Committee members, ex officios and outside experts
- Sub-groups focused on each chapter
- Small leadership group
- In person meetings and teleconferences
- Public comment period
- Full committee approval

U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services

Report of the Secretary's Advisory Committee on Genetics, Health, and Society

April 2008

The report called for more oversight of genetic testing, citing "significant gaps" in validating the tests' usefulness, especially those sold directly to consumers

Recommendation 1 of 5

- **To improve clinical laboratory quality, the Centers for Medicare & Medicaid Services should require proficiency testing (PT) of all nonwaived laboratory tests for which PT products are available.**

- **HHS should support innovations in the way PT is performed, and the Department should also ensure funding for the development of reference materials and methods for assay, analyte, and platform validation; quality control; performance assessment; and standardization.**

2 of 5

- **To help close the gaps in oversight related to clinical validity, which would help assure the appropriate use of laboratory tests, the Food and Drug Administration (FDA) should address all laboratory tests, regardless of how they are produced (i.e., as a commercial test kit or laboratory-developed test), in a manner that takes advantage of its current experience.**

3 of 5

- **To enhance the transparency of genetic testing and assist efforts in reviewing the clinical validity of laboratory tests, HHS should appoint and fund a lead agency to develop and maintain a mandatory, publicly available, Web-based registry for laboratory tests.**

4 of 5

To better understand the usefulness of genetic tests, HHS should:

- **Create and fund a public-private partnership to evaluate the clinical utility of genetic tests,**
- **Develop a research agenda to address gaps in knowledge, conduct public health surveillance to assess the health impact of genetic testing,**
- **Help advance the appropriate use of electronic health records as a resource for assessing clinical utility and quality of health care**

5 of 5

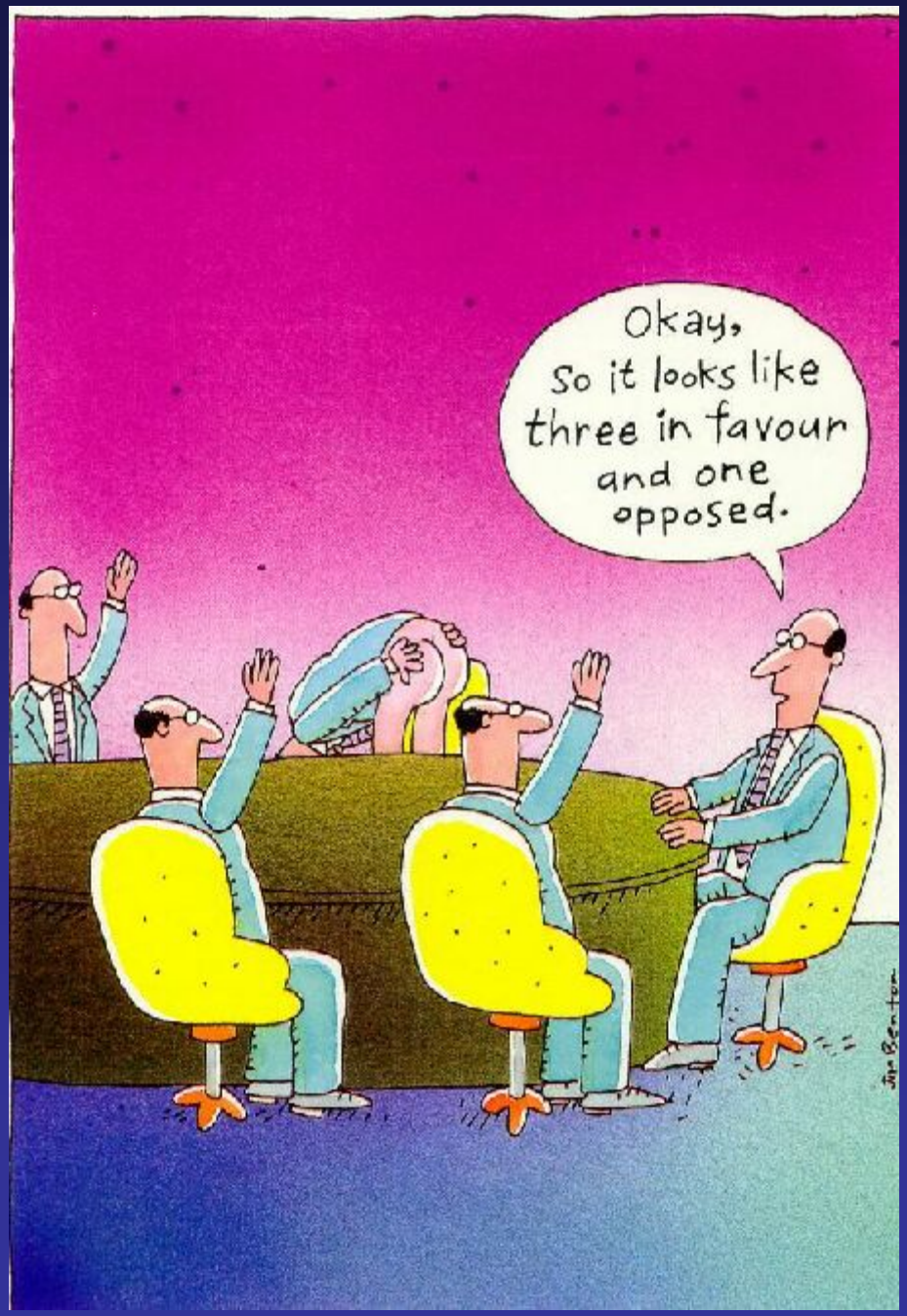
To meet the educational needs of health professionals, public health workers, patients, and consumers, HHS should:

- **Support efforts to identify education or training deficiencies in each of these groups and**
- **Support research and development of effective clinical decision support systems.**
- **FDA should prepare a guidance document articulating the scope of its regulation of clinical decision support systems.**


© Original Artist
Reproduction rights obtainable from
www.CartoonStock.com
MIKE SHAPIRO
"Whoever said 'The only thing we have to fear is fear itself' never had to face a room full of angry ~~shareholders.~~" stakeholders

Where do we go From Here?

- Implementation at the Secretary's discretion
  - Signs that the department is thinking about following some recommendations
- Reference for policymakers and stakeholders
- Conversation starter


Okay, So it looks like three in favour and one opposed.
Jim Benton