Citizen's Participation in Genetic Testing

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Consumer Task Force on Genetic Testing

- Members of disease-specific advocacy organizations
- Engage over the years in meetings, white papers, reports, commentary
- Core of the planning committee for Eyes on the Prize: Truth telling about Genetic Testing

Issues of Concern

Science

- *Personalized Health Care:* striving toward personalized therapies and interventions based on genetic data is creating tensions in the system – this has rare disease implications
- *Biobanks:* they are not regulated, the resource is often not shared. How to create virtual indices, Genetic Alliance BioBank model
- *Registries:* Registries should be detailed repositories for the methods, volumes and oversight of tests

- *Evidence:* how much clinical evidence is enough? Are the pressures to bring tests into the marketplace overriding the scientific need for evidence? Or are demands for evidence unnecessarily slowing down the approval process? All tests cannot be held to a single standard – there are legitimate variables in the need for clinical data. What role does post-market data play in collecting evidence?
- *Study Design:* predictable, well-designed studies, streamline to move tests from research to clinical practice.

Oversight

- *Regulatory Authority:* who has the regulatory authority for genetic testing? What should be the role of the FDA, CLIA (under CMS), and the FTC? How can the regulatory scheme be coordinated so that it promotes transparency, predictability, and clarity?
- *Professional Organizations:* what role should they play in regulatory oversight? Given that participation in professional organizations is voluntary, how much impact can they have on “bad actors?”

- *Risk-Based Regulation:* acknowledges the fact that some tests pose more risk to patients and society than others.
- *Proficiency Testing:* critical role of proficiency testing in achieving superior quality control. How to increase the amount of proficiency testing without placing an undue financial burden on small laboratories?
- *Direct-to-Consumer Tests:* distinguish between marketing and testing. How can the public be protected from fraudulent or exaggerated claims?
- *Test Interpretation:* who determines clinical utility?

Access

- *Rare Diseases:* CETT model has been successful. Can it be expanded?
- *Resource Allocation:* equal access to testing and treatments from rare diseases to international and developing world issues.
- *World Health:* how can the transfer of genomics technology to the developing world be streamlined?

Reimbursement: reimbursement has been called the "ultimate bar", the definitive regulation. But do the payers really understand the value of genetic testing? Is this even the right structure for the healthcare system? Value-based pricing works for drugs, can it work for diagnostics, and ultimately, can it work for the entire system interminably?

Commercialization

- *Costs and Value:* how do we determine the value of a test?
- *Incentives:* how to make sure the CETT program will be expanded to take up all of the orphaned orphans

Social Issues

- *Genetic Discrimination:* strong support for the passage of GINA.
- *Medical Record Aggregation:* would the public support large databases, or would privacy concerns override perceived benefits?
- *Tensions between the Product and the Process*: technology takes great leaps but behavior has a slow, iterative rate of change.
- *Intellectual Property:* How to craft an intellectual property policy so that it encourages investment while ensuring adequate access to data? Where should the pre-competitive bar be set?

- *IP Models:* other industries have wrangled with some of the issues that are currently facing the genomics industry. What lessons have been learned in other industries that can be applied to the genomics industry?
- *Public- Private Partnerships:* strong support for public-private partnerships. These types of arrangements could go a long way toward relieving the pressures on the current system.
- *Role of Patients and the Advocacy Community:* considered the bridge between the scientific community and the public. It is crucial that they take great care with the messages that they bring to the public.

Organization for Economic Co-operation and Development

Guidelines for Quality Assurance in Genetic Testing

- Patient input into guidelines
- Health outcomes as the focus
- Comprehensive sections on many important aspects of testing

Conclusions

- NIH put more requirements on funding – require various standards so that basic and translational research is more informative, achieves evidence standards efficiently.
- Discourse with, and responsiveness from, federal agencies that have jurisdiction over genetic testing.
- Coordination of jurisdiction and activities of CMS and FDA, and other relevant agencies.
- Clarity and predictability – current process is not conducive to a growing, or stable, marketplace.
- A risk-based regulatory system is desirable, with the caveat that allowances need to be made for volume.
- Direct-to-Consumer tests need special oversight.

Conclusions, continued

- Public-Private partnerships are desirable as a means for ensuring the pipeline from discovery to tests is efficient and effective.
- Education (at all points in the process) is desirable.
- We need outcomes-data collections and clear evidence bars.
- The industry must have the means to rid itself of “bad actors”, but regulation of the industry should not be based on bad actors.
- A mandatory registry must be established and managed by either a public private partnership or government agency.

Action items

- Advocate for enhanced CLIA - PT.
- Promote mandatory registry.
- Convene summit on reimbursement issues.
- Explore concepts of risk.
- Educate policymakers, patients, and clinicians.
- Further examine the global perspective.
- Work to pass GINA – **DONE!**