

Personalized Medicine



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Policy Areas Under Evaluation

1. Regulation of therapies and diagnostics by FDA, CMS;
2. Reimbursement of therapies and diagnostics by CMS and private insurance companies;
3. Genomic diagnostics, intellectual property and related emerging patent issues (PTO);
4. Patient privacy;
5. Information technology and issues of electronic patient records and associated data/databases;
6. Economics of personalized medicine;
7. Personalized medicine technology/tools; and
8. Patient, physician and public education.



Summary of Input

- Since January 2007, heard briefings and public and private testimony by representatives from **over 75** Federal agencies and institutes, companies, universities, health providers, payors, and venture or law firms.
- ✓ Panels and discussion at PCAST meetings in January, April, and September, 2007
- ✓ Subcommittee workshops in San Francisco (July, 2007) and Boston (November, 2007)



PCAST Study Update

- Approach:
 - Engage government-private sector dialogue to facilitate and coordinate technology advancement, while protecting patients/consumers;
 - Detail policy recommendations affecting immediate and near-term research and commercialization;
 - Contemplate vision for longer term implications for, and implementation by, public/private research enterprises and healthcare system.
- Policy activities and recommendations generally are provided at high level
- Study is ongoing during period of meaningful changes at FDA, CMS, PTO



Study Topics: January 8, 2008

The GeneTests¹ website identifies more than 1,000 clinically available gene-based tests, plus 300 available for research purposes only.

Today we will look at the effect of these, as well as other Personalized Medicine applications, upon:

- Patient privacy, advocacy, education;
- Physician education, training;
- Direct-to-consumer; and
- Regulation

1. www.genetests.org