

Personalized Medicine:

A Call for Action

Harvard Medical School-Partners Healthcare Center for Genetics and Genomics



M. Kathleen Behrens, Ph.D.

Member, President's Council of
Advisors on Science and Technology
(PCAST)

November 29, 2007



PCAST Background

- Presidentially appointed, 34-member advisory board on science and technology;
- Co-chairs: *John H. Marburger, III*, Director, Office of Science and Technology Policy and
E. Floyd Kvamme, Partner, Kleiner Perkins Caufield & Byers;
- Executive Director: *Celia Merzbacher, Ph.D.*, Assistant Director for Technology R&D, Office of Science and Technology Policy;
- PCAST brings perspective of the private sector to the President;
- Briefings by and recommendations often affecting agencies;
- Membership, studies and public presentations available at <http://www.ostp.gov/PCAST/pcast.html>



PCAST Personalized Medicine Subcommittee

Dr. M. Kathleen Behrens	Chair, Consultant and GP, RS Investments
Mr. E. Floyd Kvamme	Partner, Kleiner Perkins Caufield & Byers
Dr. Charles J. Arntzen	Florence Ely Nelson Regent's Professor, Arizona State University
Dr. Robert A. Brown	President, Boston University
Dr. G. Wayne Clough	President, Georgia Institute of Technology
Dr. Nancy Dicciani	President & CEO, Specialty Materials, Honeywell International
Dr. Marye Anne Fox	Chancellor, University of California, San Diego



PCAST Personalized Medicine Subcommittee (cont.)

Dr. Martha Gilliland	Sr. Fellow, RAND: Council for Aid to Education
Dr. Bernadine Healy	Health Editor and Columnist, U.S. News and World Report
Dr. Martin Jischke	President Emeritus, Purdue University
Mr. Steven Papermaster	Chairman, Powershift Ventures
Dr. Luis M. Proenza	President, University of Akron
Dr. Daniel A. Reed	Director of Scalable and Multicore Computing, Microsoft Corporation (<i>effective 12/3/07</i>)
Mr. Joseph Tucci	Chairman, President & CEO, EMC Corp.
Dr. Tadataka Yamada	President, Bill and Melinda Gates Foundation



Personal Background

- 27 years experience in securities and venture industries;
- Analysis, creation and financing of biotechnology, medical device and services companies, as well as other healthcare and technology companies;
- Director of public and private companies;
- NVCA board member, President, Chair for 7 years; STEP board member 8 years;
- PCAST member since 2001.



PCAST Study on Personalized Medicine: Schedule of meetings

- Study commenced with public PCAST meeting January, 2007;
- Additional presentations by experts at April and September, 2007 public PCAST meetings;
- Subcommittee meeting in San Francisco, July, 2007;
- Subcommittee meeting in Boston, November, 2007;
- Presentations planned for public PCAST meeting in Washington, D.C., January 8, 2008.



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;
8. Patient, physician and public education.



Summary of Input

Between January 10, 2007 and November 28, 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.



Participants from Federal agencies

Health and Human Services (HHS) Deputy Secretary

Counselor for Science and Public Health of the Office of the Secretary, HHS

Director of the National Heart Lung and Blood Institute, NIH

Director of the National Institute of General Medical Sciences, NIH

Director of the National Institute of Human Genome Research, NIH

CMO of Medicare and Medicaid Services (CMS) and Director, Office of Clinical Standards & Quality (OCSQ)

FDA Deputy Commissioner for Operations and Chief Medical Officer, Acting Center Director, Center for Drug Evaluation and Research (CDER)

Program Director, Personalized Healthcare Initiative, Office of the Secretary, HHS

Medical Officer, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality (AHRQ)

National Coordinator, Office of the National Coordinator for Health Information Technology, HHS

Director, Technology Center, United States Patent and Trademark Office

Director, Biomedical Laboratory Research and Development Services, Veterans Health Administration

Acting Chief Health Informatics Officer, Veterans Health Administration

Security Advisor to the VA Office of Information and Technology



Participants from Academia

- Dr. Raju Kucherlapati, Scientific Director, Harvard Partners Center for Genetics and Genomics
- Dr. Elaine Mardis, Co-Director Washington University Genome Sequencing Center
- Dr. Mark McClellan, Director, Engelberg Center for Healthcare Reform, Brookings Institute
- Dr. Kathryn Phillips, Prof. Health Economics and Health Services Research, Dept. of Pharmacy, UCSF
- Dr. Ernst R. Berndt, Professor, Sloan School of Management, MIT, NBER
- Dr. Henry Grabowski, Professor of Economics, Duke University
- Mr. Richard Carlson, Clin. Prof. and Sr. Advisor, Resource Center for Health Policy, School of Public Health, University of Washington
- Ms. Gail Javitt, Law and Policy Director, Genetics and Public Policy Center, Johns Hopkins University



Participants from Legal/Venture Firms

Mr. Vernon Norviel, Wilson Sonsini Goodrich & Rosati

Mr. Michael Shuster, Fenwick & West LLC

Mr. Robert Blackburn, DNA/*ex*

Mr. John Barton, Stanford University Law School

Mr. Nick Littlefield, Foley & Hoag LLC

Ms. Barbara Caufield, Affymetrix, Inc.

Mr. Brook Byers, Kleiner Perkins Caufield & Byers

Dr. Fred Cohen, Texas Pacific Ventures Group

Ms. Sue Siegel, Mohr Davidow Ventures

Mr. Michael Goldberg, Mohr Davidow Ventures

Dr. Michael Hunkapillar, Alloy Ventures



Participating Companies

Abbott Laboratories

AstraZeneca

BD Biosciences

Johnson & Johnson

GE Healthcare

Eli Lilly

Lab Corp

Merck & Co.

Quest Diagnostics

Novartis/Chiron

Philips

Pfizer, Inc.

Siemens

Roche

Sanofi-Aventis



Participating Companies (cont.)

Affymetrix, Inc.

23andMe, Inc.

Celera Diagnostics

Navigenics, Inc.

Genomic Health, Inc.

Helicos Biosciences Corp.

Cerner Corp.

Luminex Corp.

IBM

Monogram Biosciences

Microsoft

Nanogen, Inc.

RiGEN, Inc.

Signature Genomic Laboratories LLC

Tethys Bioscience

Third Wave Technologies, Inc.



Payors and Providers

EDS

HCA Inc.

Kaiser Permanente

Marshfield Clinics

Medco Health Solutions, Inc.

Partners Healthcare

RTI Health Solutions

United Healthcare Group

Wellpoint, Inc.



Additional topics to be considered

- Patient privacy, advocacy, education;
- Physician education, training;
- Direct-to-consumer;
- Trade associations;
- Further assessment of technology/tools.



Schedule for completion

- Public and private briefings, January 2008;
- Draft report, Spring 2008;
- Possible agency and private sector workshop, Spring 2008;
- Recommendations to President, Summer 2008.



PCAST Study Perspective

- Engage government-private sector dialogue to facilitate and coordinate technology advancement, while protecting patients/consumers;
- Detail policy recommendations affecting immediate and near term technology and product developments;
- Contemplate vision for longer term implications for and implementation by public/private research enterprises and healthcare system.



PCAST Perspective

- Policy activities and recommendations generally provided at high level;
- PCAST Personalized Medicine study ongoing during period of meaningful change for regulation by FDA, CMS, PTO;
- Government-industry interactions providing more detailed insights and involvement than typical for PCAST policy report and recommendations.

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