

The Personalized Medicine Coalition (PMC), representing a broad spectrum of academic, industrial, patient, provider, and payer communities, seeks to advance the understanding and adoption of personalized medicine concepts and products for the benefit of patients.

SPRING 2007

Letter from the Executive Director Secretary Michael Leavitt Embraces the Goal of Personalized Medicine



At its Third Annual Keynote Luncheon Address on the State of Personalized Medicine at the National Press Club in Washington, DC, on March 23rd, the Personalized Medicine Coalition (PMC) heard U.S. Department of Health and Human Services (HHS) Secretary Michael Leavitt call for seizing “opportunities we’ve never had before” to usher in a new era of molecular-based medicine. Based on a year of study and analysis, he envisioned healthcare characterized by “the right treatment, to the right patient, at the right time – every time.”

As we know, this is the mantra of personalized medicine, and indeed of the PMC since its inception. Although we are still a long way from the transformation of healthcare promised by molecular medicine, it is a clear sign of progress when the Secretary of HHS adopts it as the goal for the healthcare system.

The PMC deeply appreciates Secretary Leavitt’s leadership in making personalized healthcare “a national priority.” The organization was honored and pleased that he chose the annual PMC event as the place to say so, accompanied by other senior government officials including Dr. Elias Zerhouni, Director of the National Institutes of Health (NIH); Dr. Francis Collins, Director of the National Human Genome Research Institute of NIH; Dr. Carolyn Clancy, Director of the Agency for Healthcare Research and Quality; Dr. Terry Cline, Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA); and Dr. Robert Kolodner, Director of the Office of the National Coordinator for Health Information Technology.

continued on page 2

PMC Responds to HHS RFI on Health Information Technology

On January 26, the Personalized Medicine Coalition (PMC) submitted comments and recommendations to the U.S. Department of Health and Human Services’ (HHS) Request for Information (RFI), “Improving Health and Accelerating Personalized Health Care Through Health Information Technology and Genetic Information in Population- and Community-Based Health Care Delivery Systems.” In its response, the PMC commented on major issue areas for HHS to consider as it seeks to support progress toward a personalized, IT-enabled healthcare system. PMC stated the importance of a shared understanding of the definition of personalized medicine and its critical linkages to Health Information Technology (HIT) to advance policy in this area; regulatory and policy recommendations to support personalized medicine; and thoughts on coverage and payment policies related to HIT and personalized medicine. PMC also provided examples of a number of ongoing scientific projects that illustrate key issues at the intersection of personalized medicine and HIT.

To read the full RFI submission, visit: http://www.personalizedmedicinecoalition.org/sciencepolicy/public-policy_hit.php. ■

PMC Meets with Secretary Leavitt to Discuss Advancing Personalized Medicine at the Government Level

In order to deliver personalized medicine’s promise of safer and more efficacious therapies, better health, and conceivably lower systemic costs, government leadership and intervention are crucial. In a meeting with U.S.

Department of Health and Human Services (HHS) Secretary Michael Leavitt on March 23rd, the Personalized Medicine Coalition presented thoughts on how the government can accelerate the adoption of personalized medicine, and the role it can play in catalyzing change and supporting innovation.

PMC has recommended that Secretary Leavitt start now by taking action within HHS, by working with PMC collaboratively going forward, and especially, by engaging all Americans in this endeavor.



Secretary Michael Leavitt, U.S. Department of Health and Human Services, addresses Personalized Medicine Coalition members and guests.

continued on page 2

ALSO IN THIS ISSUE:

SACGHS: Request for Public Comment	2
PMC Keynote Event Archive at The Age of Personalized Medicine	3
PMC in the Press	3
PMC Welcomes New Members	3
Upcoming Events	4

Letter from the Executive Director *continued from page 1*

In particular, Secretary Leavitt noted that HHS is focused on:

- Reviewing privacy protections as Health Information Technology (HIT) is increasingly adopted;
- Ensuring that genetic tests are “accurate, valid, and useful” by assigning responsibilities among HHS agencies to support that goal;
- Allocating \$15 million to create a “network of networks” to allow researchers to match treatments and outcomes; and
- Developing recommendations to identify HIT standards for genetic test information on electronic health records.

These initiatives, of course, supplement ongoing NIH-funded research across the Institutes with implications for personalized medicine; the Critical Path effort at the Food and Drug Administration to augment the pipeline leading to new medical products, including forthcoming regulatory guidance on the co-development of drugs and diagnostic tests; and the combined effort between the Centers for Disease Control and Prevention and the National Cancer Institute to define the leading 100 genetic variants of public health significance.

At the luncheon, Secretary Leavitt called for the Congressional passage of the Genetic Information Nondiscrimination Act (GINA), emphasizing that President Bush looked forward to signing the measure. He also publicly recognized the work of PMC Board Member Sharon Terry and the Coalition for Genetic Fairness, of which PMC is a member, on behalf of the bill.

The PMC is continuing to coordinate with the Secretary’s team to advance this Initiative, and has pledged its support to assist its efforts. We share the Secretary’s view that this is “the work of a generation,” and look forward to an acceleration of the pace of personalized medicine so that all Americans may enjoy better healthcare in the future. ■

—Edward Abrahams
Executive Director, Personalized Medicine Coalition

SACGHS Report: Request for Public Comment

The Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) is requesting public comment on a draft report to the Secretary of the U.S. Department of Health and Human Services (HHS), “Realizing the Promise of Pharmacogenomics: Opportunities and Challenges.”

According to the request, “SACGHS identified the emerging field of pharmacogenomics as a high study priority because it holds significant promise for improving the productivity of the drug development pipeline, increasing the safety and effectiveness of drugs by reducing adverse reactions, and ultimately resulting in more efficient use of drugs.

“The draft report describes opportunities and challenges in pharmacogenomics in three major areas: 1) research and development; 2) ‘gatekeepers,’ i.e., those who are involved in facilitating the progression of pharmacogenomics; and 3) implementation of pharmacogenomics to improve outcomes in clinical and public health practice.”

Comments must be submitted by June 1, 2007 to be considered for the final report. PMC’s Clinical Science and Public Policy Committees are currently reviewing the report in anticipation of submitting comments on behalf of PMC.

To read the full draft report, and to view specific questions for which the Committee is requesting feedback, visit

http://www4.od.nih.gov/oba/SACGHS/public_comments.htm. ■

PMC Meets with Secretary Leavitt to Discuss Advancing Personalized Medicine at the Government Level *continued from page 1*

PMC has suggested the following actions:

- > Engage the appropriate HHS agencies:
 - Support personalized medicine across all relevant HHS agencies and create an interagency task force on personalized medicine;
 - Re-engage and fund FDA efforts in personalized medicine;
 - Fund relevant research and large-scale translational initiatives at NIH; and
 - Fund personalized medicine efforts at AHRQ and CMS, including the creation of a strategy to incentivize preventive, predictive, and personalized healthcare.
- > Support the enactment of the Genetic Information Nondiscrimination Act (GINA).

> Develop and put in place a Health Information Technology (HIT) infrastructure to improve the quality and efficiency of healthcare.

> Convene a Summit Meeting on “Leveraging Multi-Sector Capabilities to Accelerate the Adoption of Personalized Medicine.”

To view the full letter from PMC to Secretary Leavitt, which includes more detail on the recommendations above, visit http://www.personalizedmedicinecoalition.org/objects/pdfs/PMC_Leavitt_CoverLetter_20070321.pdf

To view a graphic representation of how the government can accelerate the adoption of personalized medicine visit

<http://www.personalizedmedicinecoalition.org/objects/pdfs/GovtAcceleratePM.pdf>.

A background document on the issues affecting the adoption of personalized medicine was prepared by PMC in advance of its meeting with the Secretary. The document covers genetic privacy and nondiscrimination; healthcare worker attitudes, awareness and education; IT implementation; regulation; and reimbursement. To view the document, visit http://www.personalizedmedicinecoalition.org/objects/pdfs/PMC_PM_Issue_20070321.pdf.

Printed copies are also available upon request. Please contact Roxanna Smith at rsmith@personalizedmedicinecoalition.org. ■

PMC in the Press

The Associated Press reported in January on the impact personalized medicine could have on warfarin dosing, a treatment for the approximately 2 million Americans with an abnormal, clot-triggering heart rhythm. Currently, doctors use trial and error to determine the right dose for each patient; receiving too little of the drug can lead to a stroke, while receiving too much can cause life-threatening bleeding. The article, "Personalizing medicine: Testing how genes affect warfarin dose," discusses studies currently underway to determine how a person's genetic makeup can be used to choose the best medicine or dose. Edward Abrahams, PMC Executive Director notes, "It's a big deal. Warfarin is a very widely used drug, it's been around for 50 years and it has all these adverse events associated with it."

In a recent *PharmaVOICE* article, "The Age of Personalized Medicine," Abrahams was recognized as a "thought leader" on the subject, along with several PMC member company executives, including Raju Kucherlapati, Ph.D., (Harvard Partners Center for Genetics and Genomics); Brian Spear, Ph.D. (Abbott); Elaine Weidenhammer, Ph.D. (Nanogen Inc.); and William Young (Monogram Biosciences). Abrahams discusses the emerging PMC agenda, including reimbursement, regulation of drug/diagnostic test co-development, and hurdles that must be overcome for personalized medicine to be realized. "What we need to do to advance the paradigm is to determine what's missing. There are a couple of areas that I think are critical. The first is that we need better economic data and better explanations of why linking therapeutics and diagnostics makes economic sense. That includes a better understanding of the business model that would support personalized medicine. The other big area is healthcare provider education," he says.

U.S. Department of Health and Human Services (HHS) Secretary Michael Leavitt unveiled his Personalized Health Care Initiative at the PMC's Third Annual Keynote Luncheon Address held on March 23rd in Washington, D.C. (read more about the event on page 1). Media coverage of the event highlighted the Secretary's vision that the combination of gene-based medical care and healthcare information technology would transform the quality, safety, and value of healthcare for patients in the future. Coverage included *Washington Times*, *Modern Healthcare*, *Healthcare IT News*, *BioIT World*, *GenomeWeb Daily News*, and *United Press International*.

For links to these and other PMC-related articles, visit the Communications section of our website at: <http://www.personalizedmedicinecoalition.org/communications/overview.php>. ■

PMC Keynote Event Archive at The Age of Personalized Medicine

Michael Leavitt, Secretary of the U.S. Department of Health and Human Services (HHS), has identified Personalized Health Care as one of his top priorities, and has outlined new steps that HHS is taking to achieving gene-based medical care combined with Health Information Technology (HIT).

Addressing members and guests of the Personalized Medicine Coalition (PMC) on March 23, 2007 — at the organization's annual gathering at the National Press Club to spotlight progress in the field — Secretary Leavitt noted that his Initiative is designed to improve the safety, quality, and effectiveness of healthcare for every patient in the United States.

The full video of the proceedings, a summary of the event, as well as photos and links to related resources have been posted at The Age of Personalized Medicine.

For more information, visit: http://www.ageofpersonalizedmedicine.org/knowledge_center/events/leavitt.asp. ■

The Age of Personalized Medicine

PMC Welcomes the Following New Members Since December 2006:

Aetna
Alliance for Aging Research
DNA Vision s.a.
IDA Ireland
KFDunn Life Sciences, a division of Aloysius Butler & Clark
Lead Horse Technologies, Inc.
Lipomics Technologies, Inc.
Marshfield Clinic
NeuroMark
Osmetech Molecular Diagnostics
Pappas Ventures
Pri-Med Institute
Stephens Investment Management

Upcoming Events

For more information regarding these and other PMC events, please visit our event calendar on the PMC website.

Board of Directors Meeting

April 18, 2007

1:00 p.m. – 4:00 p.m.

1225 New York Avenue, NW

Washington, D.C.

Committee Meeting:

Public Policy Committee Meeting

April 18, 2007

10:00 a.m. – 12:00 p.m.

1225 New York Avenue, NW

Washington, D.C.

Special presentation: Centers for Disease Control and Prevention's *Beyond Gene Discovery Initiative*

Sponsored Events:

April 25-26 | *DxMA's 29th Annual Conference*

Organized by: Diagnostic Marketing Association

Venue: Millennium Knickerbocker Hotel, Chicago, IL

For more information, visit <http://dxma.org/extras/2007SpeakerHighlights>

May 2-3 | *Developments in Gene Expression Profiling*

Organized by: Active Communications International (ACI)

Venue: Copthorne Tara Hotel London Kensington, London, UK

For more information, visit http://www.personalizedmedicinecoalition.org/objects/pdfs/Personalized_Medicine_Coalition_flyers.pdf

As a member of the Personalized Medicine Coalition, you are entitled to a 15% discount on registration price for the *Developments*

in Gene Expression Profiling event if you book before the 20th of April 2007. Please call Melanie Mulazzi at +44 20 7368 1654 or email her at mmulazzi@acius.net if you want additional information or if you want to register.

November 13-14 | *3rd Annual Burrill Personalized Medicine Meeting*

Organized by: Burrill and Company

Location: San Francisco, CA

November 29-30 | *Personalized Medicine: A Call for Action*

Host: Harvard Medical School-Partners HealthCare Center for Genetics and Genomics

Venue: The Conference Center at Harvard Medical, Boston, MA

Sign up

To receive the PMC Newsletter and other announcements from PMC, sign up at our website: www.PersonalizedMedicineCoalition.org