PMC Personalized Medicine Coalition

Member Newsletter

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 2006

"We are in the right place at the right time"

When a handful of companies, academic institutions, and patient advocacy groups publicly launched the Personalized Medicine Coalition at the end of 2004, our goal, we thought at the time, was rather ambitious. Recognizing that science and technology alone would be insufficient to usher in a new medical paradigm, we wanted to create an educational and advocacy organization that could, if not create a friendlier political and economic landscape, at least ask the right questions about what would be necessary to realize the power and promise of personalized medicine.

In a little over a year the PMC has grown from fewer than 20 members to over 70, but more importantly, our wish to get the opinion leaders to think about personalized medicine, at least judging by what we hear in Washington from both prominent Republicans and Democrats as well as from academic and industry leaders, has grown far beyond the expectations of the founding members.

Three examples:

First, Health and Human Services (HHS) Secretary Michael Leavitt delivered a major speech at BIO in Chicago in April in which he said that he plans to devote the last 1,000 days of the Bush Administration to realizing the vision of personalized medicine by changing the way drugs are discovered, developed, and regulated in order to move from reactive to predictive medicine. Basing his plan on creating a "voluntary national genetic profile database" that could be used to streamline clinical trials, he also contends that it will lead to more patient-centered and preventive medical care as well. With FDA, CMS, and NIH all reporting to him, this is not insignificant.

Second, Senator Barak Obama plans to introduce later this year the "Genomics and Personalized Medicine Act of 2006," a comprehensive bill to improve and expand the use of molecular tests and therapeutics, the backbone of personalized medicine. Focusing on the research, regulatory, and reimbursement responsibilities of the federal government, the bill's overarching purpose is to facilitate the advancement of personalized medicine.

continued on page 2

J. Brian Munroe Elected President and Chairman of Personalized Medicine Coalition for Second Term

The Personalized Medicine Coalition (PMC) is pleased to announce that J. Brian Munroe has been re-elected president and chairman by the PMC Board of Directors. Munroe was recently appointed as vice president of federal affairs at WellPoint, the largest publicly traded commercial health benefits company in the United States, as measured by size of membership. Simultaneously, WellPoint has joined the PMC, thereby broadening the organization's already-diverse representation of personalized medicine constituencies to include the payer community.

"As a member of the PMC, WellPoint looks forward to participating in the emerging opportunities to improve the health care system that will come from molecular-based research," Mr. Munroe said. "WellPoint views the PMC as the place where the relevant issues surrounding personalized medicine can be discussed and as the agent to incorporate good biology into that discussion."

To read the full press release, please click here. ■

Biobanking Website Launched

It is well accepted among the scientific community that the availability of large numbers of high quality, clinically annotated biospecimens (such as tissue, blood, etc.) are a critical resource for genomics-based research and the development of personalized medicine products. And patients have a long history of generously donating such samples, motivated by the desire to advance research and to help others avoid the pain and suffering of disease. Now, there's a dedicated web-based portal (http://www.biobankcentral.org) to engage the public in this endeavor.

BioBank Central will assist researchers who require biological materials for their studies, encourage the donation of tissue and blood by patients, and inform the public about the critical role of biobanks – also known as biorepositories – in enabling modern biomedical research. *FasterCures/The Center for Accelerating Medical Solutions*, a non-partisan, nonprofit action tank, is hosting the new BioBank Central website. Sponsors of the site include PMC members IBM and Affymetrix, Inc., as well as Bioaccelerate Holdings Inc. and Invitrogen Corporation.

Leaders in the biobanking community have been organizing for several years to ensure

continued on page 2

ALSO IN THIS ISSUE:

Letter from the Executive Director

continued from page 1

Third, PhRMA's new president and CEO, Billy Tauzin, noted this month that personalized medicines "are going to be the success model of the future," suggesting new thinking within the ranks of the pharmaceutical industry about the future of one-size-fits-all drugs.

We know that the science and technology that underpin personalized medicine are proceeding rapidly with new discoveries announced almost every day (check our website's homepage). We also are aware, moreover, that personalized medicine could be more widely applied than it is even today. But we also know that there are too few truly targeted therapies on the market, Herceptin® and Gleevec® notwithstanding. Many of our members, especially the scientists among them, caution us not to permit hype to drive expectations regarding what the science and technology can realistically deliver, especially absent a business model that fully supports the advancement of personalized medicine.

Yet, the PMC welcomes the high profile, potentially high impact political attention our agenda is receiving in Washington. Because the PMC has brought all the stakeholders together, including payers, providers, and patients, it is positioned to help HHS, the Congress, if not the pharmaceutical industry as well, work through some of the really tough issues that will determine how and when personalized medicine becomes a reality, ranging from creating financial incentives for the co-development of diagnostic and therapeutic products to introducing supportive regulatory and reimbursement models that will lead to the implementation of personalized medicine.

Our Landscape Analysis and Strategic Plan, currently in the field and due to be released at the end of the year, by providing insight into how personalized medicine products and services are and will be received, will also allow the PMC, we believe, to better inform if not channel the emerging discussion.

In addition to our educational seminars and conferences that explore various aspects of how personalized medicine is changing the health care landscape, we have also organized task forces on a number of public policy issues, and invite your participation. They include, in addition to establishing principles that should define reimbursement in the new era of personalized medicine, task forces on Health Information Technology (HIT), FDA's Critical Path, creating financial incentives for the co-development of diagnostic and therapeutic interventions, and evidence-based medicine.

Members of the PMC are encouraged to participate by signing up on our website for these task forces, which supplement our committees on policy, science, and communications.

A growing organization that recognizes that there are many more questions than answers raised by the disruptive technology we call personalized medicine, the PMC is only as strong as its members' commitment. We are in the right place at the right time. ■

—Edward Abrahams

PMC in the Press

In the February issue of *Biotechnology Healthcare*, Andrew C. von Eschenbach, M.D., acting commissioner of the U.S. Food and Drug Administration, speaks about the FDA's view of personalized medicine and its importance to improving health care for patients, echoing the PMC's mission. The article, "FDA Spades Field for Personalized Medicine," also includes thoughts from Edward Abrahams, Ph.D., PMC Executive Director, and PMC Board Member, Geoffrey Ginsburg, M.D., Ph.D., on the importance of third-party payment and of incorporating genomic data into diagnostics and delivery of medication.

The PMC's second annual keynote luncheon address with Dr. von Eschenbach on March 6th in Washington, D.C., drew large media attention from newspaper and trade publications. The April 2006 issue of *Pharmaceutical Executive* magazine highlighted Dr. von Eschenbach's speech as well as the PMC, saying: "If the Personalized Medicine Coalition accomplishes its goals, no one will talk about 'personalized' medicine in the future because medical care tailored to the patient's genomics and molecular make-up will be the norm in clinical practice."

For links to these and other PMC-related articles, including *The Palm Beach Post*'s, "Researchers strive to tailor drugs to specific individuals," *PharmaVOICE Views*', "Building on Momentum," *Modern Healthcare*'s, "Testing the limits of care," and *InformationWeek*'s, "A Pill, A Scalpel, A Database," visit the Communications section of our website at: *www.PersonalizedMedicineCoalition.org/communications/overview.php*. ■

Biobanking Website Launched

continued from page 1

that the appropriate resources are in place. The National Cancer Institute has hosted numerous community symposia on the subject, sponsored surveys of the field, and established the Office of Biorepositories and Biospecimen Research (OBBR) to enable the adoption of standards that will enhance the overall quality and availability of biospecimens. IBM has organized and hosted four global Biobanking Summits to address the technology, financial, ethical, and legal challenges facing the biobank community.

The BioBank Central website, built in partnership with Feinstein Kean Healthcare, also provides a working group venue, patient and public education programs, and a forum for international collaboration and harmonization of best practices. ■

PMC Responds to British Royal Society on Personalized Medicine Prospects

Last year, the United Kingdom's national academy of science, the Royal Society, posted a report on its website entitled "Personalized Medicine: hopes and realities" that gave a sobering assessment of the field and its prospects. The report stated that pharmacogenetics currently has little impact on clinical practice and is "unlikely to revolutionise or personalise medical practice in the immediate future." The report also discussed the need for large clinical trials, regulatory changes, and education of health care professionals and the general public about pharmacogenetics. Several pharmacogenetic products may enter mainstream health care over the next 10 to 20 years, the report concluded.

In response, PMC Board Member Geoffrey Ginsburg, M.D., Ph.D., and his colleague Misha Angrist, Ph.D., both of Duke University, wrote an article entitled "The Future May Be Closer Than You Think: A Response from the Personalized Medicine Coalition to the Royal Society's Report on Personalized Medicine," which will be published in the next issue of the *Personalized Medicine* journal. In the article, the authors,

continued on page 4

PMC Task Forces

The PMC has established task forces to help it shape positions on the issues surrounding personalized medicine and present them in the public square. The PMC has created the following task forces:

Critical Path
Chair, Wayne A. Rosenkrans, Jr., Ph.D., AstraZeneca Pharmaceuticals

Financial Incentives for Personalized Medicine
Co-Chair, Audrey Phillips, Ph.D., Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Co-Chair, Michael Stocum, MS, Personalized Medicine Partners, LLC

Genetic Information Non-discrimination Act (GINA)
Chair, Sharon Terry, Genetic Alliance

Health Information Technology (HIT)
Chair, Brett J. Davis, IBM Healthcare and Life Sciences

Obama Bill
Chair, Robert Wells, Affymetrix, Inc.

Reimbursement Principles
Co-Chair, Patricia A. Deverka, M.D., MS, MBE, Duke University

Co-Chair, Patrick Terry, Genomic Health, Inc.

The PMC encourages its members to participate on these task forces. For more information and to sign-up up for a task force please visit the PMC website Task Force page at http://www.personalizedmedicinecoalition.org/sciencepolicy/task_forces.php

Sign up

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

www.PersonalizedMedicineCoalition.org.

Acting FDA Commissioner Supports Personalized Medicine

Andrew C. von Eschenbach, M.D., acting commissioner of the U.S. Food and Drug Administration (FDA), told attendees of the PMC's second annual public policy luncheon that his agency is taking steps to encourage the development of safe and effective medical treatments based on the concepts of personalized medicine. He also promised to make faster drug approval a high priority during his tenure at the FDA.

At the PMC-hosted event at the National Press Club in Washington, D.C., on March 6, Dr. von Eschenbach said, "For most Americans, the concept of personalized medicine is still somewhat visionary, but it's a complex subject that we must advance." His talk, "The Molecular Metamorphosis: Personalized, Predictive, and Preemptive Medicine" was an eloquent call for a new medical paradigm, underlining the PMC's essential message that collectively we can dramatically improve health care in the 21st century based on an emerging understanding of the molecular basis of disease.

Dr. von Eschenbach has long advocated speedier approval of diagnostic tests and treatments for cancer. At the PMC meeting, he discussed the FDA guidelines issued in January that facilitate producing and testing experimental treatments. He also said that the FDA is reexamining the agency's requirements for clinical trials.

"Today's clinical trial regimens are expensive, too lengthy, and do not deliver all the answers that patients and physicians need," he said. However, he added that a more rapid approval process "does not mean a reckless process."

A video archive of the talk is available at the PMC's website: *http://www.personalizedmedicinecoalition.org/programs/von_eschenbach_pmc_video_wmv.php* ■

The Case for Personalized Medicine

PMC is currently drafting a comprehensive review article, "The Case for Personalized Medicine," assessing the state of personalized medicine and the evidence that it will become an integral part of the health care system.

Personalized medicine has the potential to:

- help physicians select the most effective therapy without having to rely on the usual trial-and-error approach
- reduce the probability of adverse drug reactions
- improve the selection of drug targets
- increase patient compliance
- reduce the time, cost, and failure rate of clinical trials
- revive drugs that have previously failed clinical trials or were withdrawn from the market
- avoid market withdrawals altogether
- shift the emphasis in clinical practices from reaction to prevention, and
- reduce the overall cost of health care.

The article examines each of these claims in turn, finding at least some evidence for each of them.

The article concludes that the case for personalized medicine currently is anecdotal rather than statistical, primarily because the field of personalized medicine is still in its early stages. Ten years ago, it did not exist, yet examples of clinical applications now accrue at a steady pace as researchers focus on it as a new paradigm. The article will soon be posted to the PMC website. ■

Personalized Medicine Landscape Analysis and Strategic Plan

The PMC is conducting a detailed assessment of the health care environment in the U.S. that will shape the discovery, development, and marketplace acceptance of new personalized medicine products and services.

Designed to assist strategic partners prepare for the future, the landscape analysis will involve a comprehensive survey of stakeholder groups including government agencies, health care delivery organizations, payers/purchasers, professional societies, patient advocacy groups, think tanks, venture capitalists, the research community, and industry.

The project's goal is to describe the existing level of knowledge and involvement in personalized medicine issues across the entire stakeholder spectrum and to gain an understanding of how personalized medicine is likely to impact the various groups over time. According to Patricia Deverka, M.D., MS, MBE, of Duke University's Institute for Genome Sciences and Policy and the principal investigator on the project, "The study will describe the likely barriers and enablers that will shape the integration of personalized medicine into clinical practice, and help decision-makers understand the personalized medicine landscape from a wide variety of stakeholder perspectives." It will also, she said, "propose recommendations for strategies and policies to help overcome any barriers that might prevent the full benefits of personalized medicine from reaching consumers and patients."

Fifteen institutions to date sponsored the landscape analysis project. Representing industry, government, academia, and patient groups, they include Abbott, Applied Biosystems, AstraZeneca Pharmaceuticals, Centers for Disease Control and Prevention, Duke University, Epstein Becker & Green, Expression Analysis, Genetic Alliance, Genomic Health, IBM, Perlegen Sciences, Pfizer, PhRMA, Quest Diagnostics, and WellPoint. ■

Upcoming Events

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

Board of Directors Meetings:

To be held at:
1401 H Street NW, Suite 200
Washington, D.C.

June 28 | 2:00 p.m. - 5:00 p.m.
September 27 | 2:00 p.m. - 5:00 p.m.
December 11 | 2:00 p.m. - 5:00 p.m.

Committee Meetings:

To be held at:
1401 H Street, NW, Suite 200
Washington, D.C.

Public Policy Committee
June 28 | 10:00 a.m. - 12:00 p.m.
September 27 | 10:00 a.m. - 12:00 p.m.
December 11 | 10:00 a.m. - 12:00 p.m.

Communications/Program Committee
June 28 | 12:00 p.m. - 2:00 p.m.
September 27 | 12:00 p.m. - 2:00 p.m.
December 11 | 12:00 p.m. - 2:00 p.m.

Clinical Science Committee
June 28 | 10:00 a.m. - 12:00 p.m.
September 27 | 10:00 a.m. - 12:00 p.m.
December 11 | 10:00 a.m. - 12:00 p.m.

Sponsored Events:

June 15-16 | *Third Annual Business of Targeted Therapeutics Executive Summit*
Organized by: Cambridge Health Institute
Venue: Westin Grand Hotel, Washington, D.C.
Featured Speaker: Johanna L. Allston, Ph.D.

July 12-13 | "*Personalized Medicine: The Changing Landscape of Healthcare*"
Molecular Diagnostics & Personalized Medicine
Organized by: Pharma IQ
Venue: The Howard Hotel, London, UK
Featured Speaker: Edward Abrahams, Ph.D.

October 23-25 | *3rd Annual Global Pharma R&D Summit*
Organized by: World Trade Group
Venue: Laguna Cliffs Marriott Resort & Spa, Dana Point, CA
Featured Speaker: Edward Abrahams, Ph.D.

Industry & Education Events:

June 14-15 | *Commercial Potential of Personalized Medicine*
Organized by: Jacob Fleming Conferences
Venue: Hotel Marriott, Brussels
Featured Speaker: Wayne A. Rosenkrans, Jr., Ph.D.

July 23-27 | "*Personalized Medicine – Educating Patients*"
2006 American Association for Clinical Chemistry (AACC) Annual Meeting
Organized by: AACC
Venue: McCormick Place Convention Center, Chicago, IL
Featured Speaker: Patrick F. Terry

PMC Responds to British Royal Society on Personalized Medicine Prospects

while recognizing the validity of some of the Royal Society report's contentions, argue that personalized medicine rather than far on the horizon is actually "being practiced in one form or another in many contexts."

The article points out that the use of two cancer drugs—Herceptin® for breast cancer and Gleevec® for chronic myeloid leukemia—are already guided by testing for specific biomarkers. Buoyed by the finding that other disease indications are sometimes discovered for drugs initially used only on a small number of patients defined by biomarkers, several major pharmaceutical companies have embraced pharmacogenetics in their drug development process. Pharmaceutical firms also are investing in pharmacogenetics in order to avoid high-profile adverse drug reactions, such as those that have occurred with Vioxx® and other COX-2 inhibitors.

In the U.S., at least, the authors see the regulatory climate as quite favorable for pharmacogenetics. For example, the U.S. Food and Drug Administration has developed voluntary guidance for pharmacogenetic data submissions and is collaborating on a project to improve the development of cancer therapies through biomarker development and evaluation.

The article, once published, will be posted to the PMC website. ■

PMC Welcomes the Following New Members:

Beechwood Consulting >>

Genelex Corporation >>

Genetics, Ethics & Policy Consulting >>

Hudson-Alpha Institute for Biotechnology >>

Nanogen, Inc. >>

The Brain Resource Company Limited >>

Tm Bioscience Corp. >>

WellPoint >>