

The Personalized Medicine Coalition is an education and advocacy organization that promotes personalized medicine concepts and products for the benefit of patients. Our members include patient, payer, provider, industrial and academic organizations that are committed to improving the quality of healthcare through personalized medicine.

Winter | 2010

Personalized Medicine is Here Now, Conference Speakers Say

BOSTON — More than 600 people attended the fifth annual personalized medicine conference at Harvard Medical School, three times as many as attended the first one. Although the conference title was *Personalized Medicine: The Time is Now*, the meeting also reflected ways in which personalized medicine is already being incorporated in healthcare.

Conference speakers presented evidence of personalized medicine's impact on millions of people, said Raju Kucherlapati, Ph.D., the Paul C. Cabot Professor of Genetics at the Harvard Medical School and chair of the conference organizing committee. Not only is the list of widely prescribed drugs that are targeted for specific populations

growing for different kinds of cancer, heart disease and other disorders, but targeted therapeutics are being adopted in the United States by large institutions whose programs touch millions of people, he said.

For example, **Medco**, the largest pharmacy benefit manager in the United States, has created a program to help advise physicians when to prescribe a diagnostic test to improve patients' health and potentially lower costs of care, said Felix Frueh, Ph.D., Medco's Vice President, Research and Development, Personalized Medicine. Medco has invested heavily in research to test the hypothesis that genetic testing

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RICK FRIEDMAN

Raju Kucherlapati, Ph.D.

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FROM THE EXECUTIVE DIRECTOR



Coalition Concludes Year on High Note

BY EDWARD ABRAHAMS

Before the House of Representatives voted on the 2009 healthcare reform package, Representative Kurt Schrader, D-Ore, introduced an amendment to ensure that the comparative effectiveness research (CER) provisions in the bill were, as he wrote in a "Dear Colleague" letter, "in step with the latest advances in genetics and molecular medicine." To make his case, he quoted NIH Director Francis Collins, who had noted that the

principles of individual variation and CER were on a "collision course" unless they were properly teamed.

In his letter to 434 Members of Congress, Representative Schrader noted that the Personalized Medicine Coalition supported his amendment, adding that the stakes were nothing less than the future of science and medical progress.

His reference to the PMC signaled

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POLICY UPDATE

PMC Sends Letters to Congress on Comparative Effectiveness Research

The Personalized Medicine Coalition encouraged lawmakers to adopt language on comparative effectiveness research that incorporates the principles of personalized medicine in separate letters to House and Senate leaders.

In its letter to Senate Majority Leader Harry Reid, D-Nev., PMC praised the inclusion in the Senate reform bill of provisions by Senators Max Baucus, D-Mont., and Kent Conrad, D-N.D. The Baucus-Conrad bill had adopted many of PMC's suggestions for incorporating personalized medicine principles to compare the effectiveness of treatments.

In a second letter to House Speaker Nancy Pelosi, D-Calif., and Majority Leader Steny Hoyer, D-Md., PMC applauded the House bills for including CER provisions that are a marked improvement over earlier versions of the House health reform legislation. PMC urged the House leadership to incorporate specific language on genetics and molecular medicine to ensure that CER is fully aligned with personalized medicine.

Separately, Representative Kurt Schrader, D-Ore., sought support for H.R. 2502, the Comparative Effectiveness Research Act of 2009, in a letter highlighting PMC's praise for his bill. "As noted by PMC," Rep. Schrader said in his letter, the bill "will ensure CER is in step with the latest advances in genetics and molecular medicine."

Copies of all three letters can be found at http://personalizedmedicinecoalition.org/sciencepolicy/public-policy_comparative-effectiveness.php.

PMC Helps Create New Personalized Medicine Blog

Pharmaceutical Research and Manufacturers of America (PhRMA) and PMC have launched a new blog that tracks key developments in personalized medicine on the Age of Personalized Medicine's website. Contributors to the blog include PMC Executive Director Edward Abrahams, Ph.D.; Raju Kucherlapati, Ph.D., Paul C. Cabot Professor of Genetics, Professor of Medicine, Harvard Medical School; Jennifer Leib, Senior Vice President, Cavarocchi-Ruscio-Dennis Associates; and PMC Public Policy Director Amy Miller, Ph.D. The blog is a joint effort of PMC and PhRMA through Innovation.org, a project designed to educate the public about pharmaceutical innovation. The blog can be viewed at <http://ageofpersonalizedmedicine.wordpress.com>.

PMC Seeks Improvements to GPMA

PMC is working with Senators Robert Menendez, D-N.J., Richard Burr, R-N.C., and Representative Patrick Kennedy, D-R.I., on a new version of the Genomics and Personalized Medicine Act, and also is seeking a House Republican to co-sponsor the measure. Among the additions PMC proposes for the legislation are incentives for business such as a research and development tax credit related to personalized medicine; an accelerated regulatory path for personalized medicine products; codifying the Personalized Healthcare Initiative within the office

of the Secretary of HHS into law, which would improve inter-agency coordination of work related to personalize medicine; and increased funding for research and other activities related to personalized medicine.

Companion Diagnostics Discussed at PMC Meetings

Lawrence Lesko, Ph.D., F.C.P., Director of the Office of Clinical Pharmacology and Liz Mansfield, Ph.D., Director, Personalized Medicine in the Office of In Vitro Diagnostics (OIVD) Center for Devices and Radiological Health (CDRH) at the FDA spoke at PMC's joint meeting of its Clinical Science and Public Policy committees in October. Dr. Lesko praised



Elizabeth Mansfield, Ph.D.; Lawrence Lesko, Ph.D.

MIKE VENTURA, BOTH

PMC's draft recommendations to FDA on the co-development of therapeutics and diagnostics. Dr. Mansfield discussed recent hiring at FDA that will increase the center's expertise in personalized medicine. Members of both committees then discussed PMC's draft recommendations, to assist FDA in developing its 2005 concept paper on the co-development of therapeutics and diagnostics into draft guidance. A workgroup of 40 PMC members completed recommendations to revise the concept paper and a list of possible white papers for the FDA to publish on the subject after the FDA urged PMC members last year to submit guidance. PMC submitted its final version of the recommendations December 9, 2009. A copy of the recommendations is available at www.personalizedmedicinecoalition.org/sciencepolicy/Comments-to-FDA-Development-of-Companion-Diagnostics.pdf.

GINA Takes Effect

The Genetic Information Nondiscrimination Act (GINA), which outlaws discrimination in employment and health insurance coverage based on employees' genetic makeup, took effect November 21, marking a key point of progress for personalized medicine. The regulations, issued by the U.S. Departments of Health and Human Services, Labor, and the Treasury, will ensure that genetic information is not used adversely in determining employment, health care coverage, or premium cost.



Personalized Medicine's Profile Grows in Washington

BY AMY MILLER | PUBLIC POLICY DIRECTOR

A change of administration and new Congress this year gave PMC an opportunity to educate policymakers on Capitol Hill and at the FDA. Building on previous successes, the Coalition made significant progress on two fronts. Congress included the principles of personalized medicine in congressional healthcare reform bills, and FDA welcomed PMC's counsel on the regulation of drug-diagnostic combinations.

PMC focused this year on ensuring that healthcare reform recognizes the emerging science of personalized medicine and is constructed in a way to encourage its development and adoption, thus enabling personalized medicine to enter the mainstream. Senate healthcare reform legislation ensures that comparative effectiveness research (CER) incorporates personalized medicine throughout the research enterprise, a victory for personalized medicine that may have widespread implications in the future, if its provisions remain in the final bill. Although the House bill also endorses personalized medicine, it limits its support by stating only that CER should include genetic and molecular subtyping.

Lawmakers are becoming more familiar with the concept of personalized medicine, as evidenced by their growing fluency with it. For example, Reps. Louise Slaughter, D-N.Y., chair of the powerful House Rules Committee, and Charles Rangel, D-N.Y., chair of the Ways and Means Committee, which oversees all federal spending, had a brief, unscripted conversation regarding CER during debate in the U.S. House of Representatives. They agreed that CER

must be "done right" by incorporating the principles of individual variation.

FDA is also responding to the growing role of personalized medicine in healthcare by making important changes at the agency. The Office of the Chief Scientist in the Office of the Commissioner chose a special advisor for personalized medicine; the FDA's Office of In Vitro Diagnostics appointed



Amy Miller, PMC's public policy director, reviews legislation on personalized medicine. In the background are Sheila Walcoff, a partner with McDermott, Will & Emery and Nick Littlefield, a partner with Foley Hoag.

Elizabeth Mansfield, Ph.D., as director of personalized medicine and hired new staff to assist her; and FDA has convened an intra-agency workgroup to develop its 2005 white paper into a draft guidance or a series of white papers on regulatory issues surrounding personalized medicine.

FDA asked PMC to offer comments on the 2005 co-developed drug-diagnostic product concept paper as part of its preparation for the new workgroup. The agency suggested PMC might be able to help the drug, diagnostic kit, and lab service communities develop a set of consensus-

based recommendations for the regulation of innovative products. On December 9, PMC sent a 14-page comment letter suggesting ways FDA could encourage development of drug-diagnostic combinations by clarifying its requirements for approving them.

Specifically, PMC requested that:

- future work focus on examples of companion diagnostics that have been submitted to FDA;
- the agency explain its decision-making regarding regulatory treatment of laboratory developed tests and IVDMIAs;
- FDA more clearly articulate the levels of evidence it requires for approval.

By bringing together the three communities most impacted by FDA action on the regulation of companion diagnostics, PMC provided the agency with unique insight and reminded it that the absence of a clear regulatory pathway for these products remains a barrier for their development.

In 2010, we anticipate increased activity in both the legislative and regulatory arenas. FDA likely will propose new, final regulations for in vitro diagnostic multivariate index assays (IVDMIs) and draft guidance for companion diagnostics. Lawmakers have already indicated interest in reintroducing the Genomics and Personalized Medicine Act and in drafting legislation on the regulation and reimbursement of high-complexity molecular and genetic tests. With healthcare reform out of the way, we expect to focus more specifically on ways that the government can assist our agenda.

Population-Based Research and Personalized Medicine Can Mesh, Conference Finds

ARLINGTON, Va — Comparative effectiveness research (CER) can incorporate personalized medicine in a way that helps improve medical care, though much work lies ahead to ensure that goal, speakers said at a conference co-hosted by the Personalized Medicine Coalition (PMC) and the **National Pharmaceutical Council** October 28.

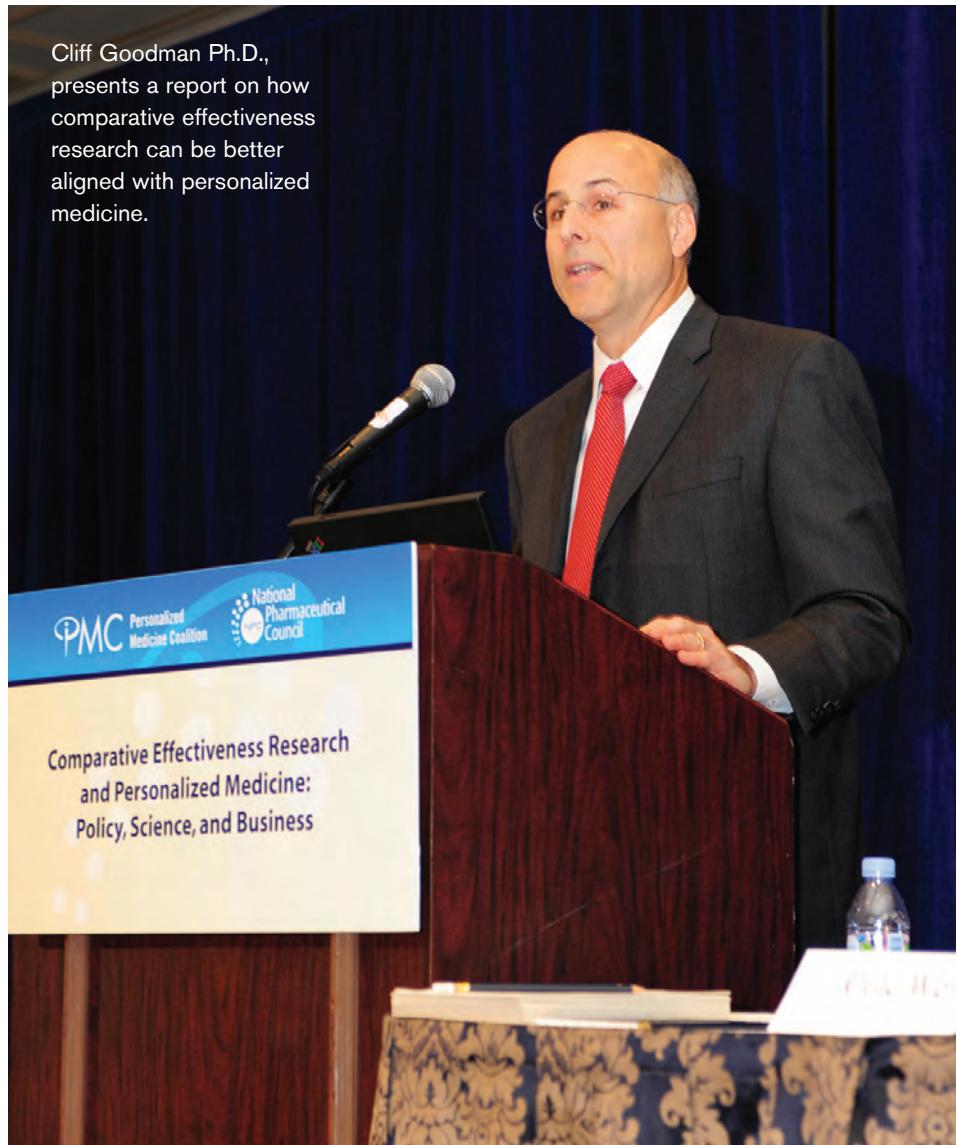
Clifford Goodman, Ph.D., vice president of the Lewin Group, kicked off the conference, *Comparative Effectiveness Research and Personalized Medicine: Policy, Science and Business*, with a report prepared for PMC that described how CER can be designed, conducted, and reported to better align with personalized medicine, achieving improved patient outcomes. CER has been oriented largely toward evaluating treatment effects across study populations, he said, while personalized medicine focuses on using individuals' genomic information and other personal traits to inform decisions about their health care. It is essential that these emerging initiatives evolve to complement, not contradict, each other.

"CER must account for the different and sometimes entirely unanticipated ways in which therapies and other health care interventions can affect individuals," Dr. Goodman told some 250 conference attendees. In that way, it can help support high-quality, evidence-based decisions for optimal patient care at both a population and an individual level, he said.

Two administration officials presented different views of the challenge posed by comparative effectiveness research. Carolyn Clancy, M.D., director of the Agency for Healthcare Research and Quality (AHRQ), said the agency is working hard to ensure that CER can be translated into clinical practice so that it meets AHRQ's mission of improving the quality, safety, efficiency, and effectiveness of health care for all Americans.

"If we're not producing information

Cliff Goodman Ph.D., presents a report on how comparative effectiveness research can be better aligned with personalized medicine.



MICHAEL VENTURA, ALL

that's useful to the clinician, then we can't possibly fulfill that mission," she said.

Janet Woodcock, M.D., director of the Food and Drug Administration's Center for Drug Evaluation and Research, saw the problem more broadly. "We don't really know how to study health care very well right now," she said. "The number of questions that need to be answered far exceeds, in my mind, our current research capacity in the United States."

Many of the questions have to do

with how best to incorporate advances in genomic science in CER, she said. Comparative effectiveness research and personalized medicine are often seen as antagonistic, but the two are actually intertwined, Dr. Woodcock added. "One will not succeed without the other," she said.

The conference drew a wide range of both speakers and attendees, including industry representatives, advocacy groups, academic researchers, venture capitalists and legislative staffers. PMC

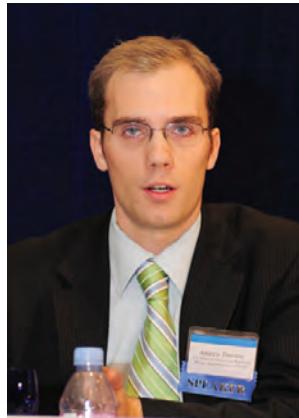
co-hosted the conference in part so that those groups could better understand and resolve the issues involved in implementing CER and its impact on personalized medicine.

As Congress continues to debate healthcare reform, it is unclear what role CER might play in a final bill. But the federal government is already working on improving and expanding such research, spurred by the allocation under the American Recovery and Reinvestment Act of \$1.1-billion among three federal agencies to conduct CER.

Congressional staff members speaking at the conference agreed on the need for a new organization to oversee CER, but differed on how it should be structured. Andrew Hu, a staff member on the U.S. Senate Finance Committee, said the Senate favors placing the organization outside government so that research is not politicized. By contrast, the House would place the organization within AHRQ.

No matter where the organization is placed, transparency, accountability and stakeholder input are key to making its recommendations credible, said Neera Tanden, senior advisor for health reform at the U.S. Department of Health and Human Services.

"No research is ever perfect,



Andrew Dawson, staff member, House Energy and Commerce Committee; Andrew Hu; Neera Tanden

but we need to ensure that we are providing quality care ... and providing information to people in a way that people can use it," she said.

In a panel focused on the opportunities for applying personalized medicine to CER, Amy Abernethy, M.D., associate director of **Duke University's** Comprehensive Cancer Institute, walked the audience through her choices in treating a 37-year-old patient with stage IIIb melanoma, and explained how full research into and knowledge of personalized medicine will help physicians better target therapies to increase survival rates.

Business leaders discussed their concerns about the impact of CER on venture capital and government reimbursement decisions. Teresa Lee, vice president of payment and health care delivery policy for **AdvaMed**, the largest medical device and diagnostic trade association, said CER results could be misleading if they reflect only the early stages in a device's life cycle. AdvaMed supports more federal investment targeted toward clinical information, she said, but there is a danger CER could potentially be used as a "blunt instrument" to deny coverage based on erroneous evaluations of the value of a human life.

Pierre Cassaigneul, president and CEO of molecular diagnostic company **XDx**, countered that done right, CER that incorporates personalized medicine holds much promise. "[It could] deliver on the promise of the health care system rather than the sick care system we have today," he said.

A copy of the Lewin report as well as slides, selected speeches and video highlights of the conference are available on PMC's website at personalizedmedicinecoalition.org/programs/cer_conference_2009/overview.php.



Janet Woodcock, M.D.; Carolyn Clancy, M.D.

Personalized Medicine Coalition 2009 Membership

Organizations new to the coalition are highlighted in **italics**

Agency Partners

Centers for Disease Control and Prevention
Centers for Medicare and Medicaid Services
National Cancer Institute
National Human Genome Research Institute
U.S. Food and Drug Administration

Clinical Laboratory Testing Services

Iverson Genetic Diagnostics, Inc.
Kimball Genetics, Inc.
Laboratory Corporation of America (LabCorp)
Laboratory for Personalized Molecular Medicine
Pathway Genomics Corporation
Quest Diagnostics

Consumer Genetic Testing Services

23andMe
DNA Direct, Inc.

Diagnostic Companies

Agendia BV
Allegro Diagnostics
Almac Diagnostics
AssureRx, LLC
Axial Biotech, Inc
BD (Becton, Dickinson and Company)
Biodesix
BioMarker Strategies
BioMérieux
BioStat Solutions, Inc.
Brain Resource Company Limited
CardioDx, Inc.
Caris Dx
Celera
Crescendo Bioscience, Inc.
Curidium Medica
Dako Denmark A/S
deCODE Genetics, Inc.
DNAVision s.a.
DxS Limited
Expression Analysis, Inc.
Expression Pathology
Gen-Probe Incorporated
GeneDx
Genelex Corporation
Genomas, Inc.
Genomic Health, Inc.
Genoptix Medical Laboratory
Interleukin Genetics, Inc.
LineaGen, Inc.
Luminex Corporation
Molecular Image, Inc.
MolecularMD
Monogram Biosciences
Nanosphere, Inc.
OncoMethylome Sciences
On-Q-ity
ParagonDx
PGx Health (A Division of Clinical Data, Inc.)

Prognomix Inc.

Proventys
Qiagen, Inc.
RedPath Integrated Pathology, Inc.
Rosetta Genomics
Saladax Biomedical, Inc.
Sequenom Center for Molecular Medicine
Siemens Medical Solutions
SomaLogic, Inc.
Tcland Expression
Tethys Bioscience
Transgenomic, Inc.
Ventana Medican Systems, Inc., a member of The Roche Group
VitaPath Genetics, Inc.
XDx Inc.

Emerging Biotech/Pharmaceutical Companies

Alper Biotech, LLC
ARCA biopharma, Inc.
BIOCRAVES Life Sciences AG
Cabernet Pharmaceuticals, Inc.
Merrimack Pharmaceuticals

Health Insurance Companies

Aetna
Generation Health, Inc.
Humana Inc.
Medco Health Solutions, Inc.

Industry & Trade Associations

AdvaMed (Advanced Medical Technology Association)
American Clinical Laboratory Association
Association of Medical Diagnostics Manufacturers (AMDM)
BIO (Biotechnology Industry Organization)
PhRMA

IT/Informatics Companies

5AM Solutions, Inc.
HP Health and Life Sciences
IBM Healthcare and Life Sciences
Lead Horse Technologies, Inc.
McKesson
Oracle Health Sciences
UNIConnect

Large Biotech/Pharmaceutical Companies

Abbott
Amgen, Inc.
Bristol-Myers Squibb Company
Eli Lilly and Company
Endo Pharmaceuticals
Genzyme Corporation
GlaxoSmithKline
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Millennium: The Takeda Oncology Company
Novartis Pharmaceuticals
Pfizer Inc

Patient Advocacy Groups

Alliance for Aging Research
Hypertrophic Cardiomyopathy Association-HCMA
National Alliance for Hispanic Health
National Brain Tumor Society

Research & Educational Institutions

AACC (American Association for Clinical Chemistry)
American Institute for Medical & Biological Engineering (AIMBE)
American Medical Association
American Society of Human Genetics (ASHG)
Association for Molecular Pathology (AMP)

Baylor College of Medicine
Brown University
Children's Hospital Oakland Research Institute
Children's Mercy Hospitals and Clinics
Cleveland Clinic Genomic Medicine Institute

College of American Pathologists
Coriell Institute for Medical Research

The Critical Path Institute (C-Path)
Duke University
El Camino Hospital
FasterCures

Fox Chase Cancer Center
Genome British Columbia
The George Washington University Medical Center

Georgetown University School of Nursing & Health Studies
H. Lee Moffitt Cancer Center & Research Institute, Inc.

Helix Health LLC
Ignite Institute
Institute of Genomic Medicine, UMDNJ-New Jersey Medical School

The Jackson Laboratory
The Dr. John T. Macdonald Foundation Department of Human Genetics, University of Miami

Marshfield Clinic
Mayo Clinic
National Coalition for Health Professional Education in Genetics (NCHPEG)

National Foundation for Cancer Research
The National Jewish Medical and Research Center

National Pharmaceutical Council
The Ohio State University Medical Center
Partners HealthCare Center for Personalized Genetic Medicine

Scripps Research Institute

University of Rochester
United States Diagnostic Standards (USDS)
University of Utah
Vanderbilt University Medical Center

Research Tool Companies

Affymetrix, Inc.
Biosearch Technologies, Inc.
Helicos BioSciences
Illumina, Inc.
Life Technologies Corporation

Strategic Partners

Arrowhead Publishers and Conferences
Boston Healthcare
Corbett Accel Healthcare Group
Defined Health
Deloitte Center for Health Solutions
Diaceutics
Diagnostic Advisors
Ernst & Young Global Biotechnology Center
Feinstein Kean Healthcare
Foley Hoag LLP
Genomic Healthcare Strategies
Growing Company Solutions, Inc.
HealthFutures, LLC
IDA Ireland
Institute for Individualized Medicine
KFDunn Life Sciences, A division of Aloisius Butler & Clark
L.E.K. Consulting
McDermott Will & Emery LLP
McKenna Long and Aldridge LLP
Nixon Peabody LLP
PAREXEL International
Personalized Medicine Partners, LLC

Premier Source

Scientia Advisors

SciTech Strategies, Inc.

Technic Solutions LLC

Townsend and Townsend and Crew LLP

Valerie August & Associates, LLC – Biotechnology Recruiter
William Blair & Company
Wilson Sonsini Goodrich & Rosati

Venture Capital

Kleiner Perkins Caufield & Byers
Lemhi Ventures
MDV-Mohr Davidow Ventures
Pappas Ventures
Third Rock Ventures, LLC

Medicare and Personalized Medicine: The Second Decade

BY BRUCE QUINN AND KALAH AUCHINCLOSS, FOLEY HOAG LLP

In their first decade, innovative personalized medicine diagnostic tests faced problems meeting insurers' coding and coverage standards for reimbursement, and uncertainty as to whether they would be reimbursed at a rate far less than the cost of developing them. In order for personalized medicine to be integrated in the medical system, appropriate procedure codes and payment systems must be developed.

The Centers for Medicare and Medicaid Services (CMS) could play a central role in resolving reimbursement issues for diagnostics. CMS convenes its third advisory panel on personalized medicine diagnostics at the end of January, where it will debate coverage issues. While CMS does not govern the actions of private insurers, private companies often follow CMS's lead in reimbursement decisions.

In the next ten years, no one doubts that personalized medicine will be front and center in healthcare, creating a critical need for improved frameworks for coverage decisions. We know that CMS is better equipped for these decisions than it was in the past. In the 1980s, the agency lacked medical expertise and could only commission a separate Office of Health Technology Assessment for medical analysis to underlie its coverage decisions. Today, CMS has a highly developed coverage group headed by Dr. Louis Jacques.

In another positive sign for personalized medicine, forward-looking approaches to support payer decision-making are starting to appear. A promising prototype has been published by the Center for Medical Technology Policy on gene expression profile tests for early breast cancer (see www.cmptnet.org). Lawrence Green, of the University of California, San Francisco, has published several articles on how to apply the results of trials to larger populations. We predict that at some point in the future, close analysis of a new genomic medical test in its clinical context will highlight whether what has been established for the validity and utility of the test leaves identifiable but unanswered questions that must be researched through a prospective randomized trial.

For now, however, CMS policy staff faces a tough challenge in figuring out how to rationalize Medicare's coverage of personalized diagnostics, which may fall under either of Medicare's separate divisions for hospitals and ambulatory services and are subject to voluminous regulations for payment, as well as disparate coding and payment rules set by the numerous local contractors who administer the national program. The result has been that first-generation personalized medicine tests have sometimes been pigeonholed into rules for older clinical laboratory tests like blood glucose or serum thyroid levels, or have fallen into the purgatory of new technologies that are deemed experimental and unpaid.

Following are some difficulties in the current system:

National coverage of personalized diagnostics. Very few molecular diagnostics have been reviewed under Medicare's national coverage system, and the level of evidence required for national coverage is high: A 2009 national coverage decision found that available evidence was inadequate to justify routine coverage of warfarin genetics, although CMS does cover this test in the context of a specific clinical trial. National coverage determinations are somewhat subjective. A coverage determination can be preceded by a very systematic literature review, but there is no similarly explicit process for officials to follow in deciding whether the review should lead to test coverage.

Coverage by local contractors. With so few national coverage decisions on personalized medicine tests, local Medicare contractors make most decisions, an approach that creates enormous uncertainty. They may use formal Local Coverage Determinations (LCDs), which CMS collects and posts on a website after a public comment period. Noridian, the Medicare contractor with the most elaborate genomic testing policy, recently noted that the field of genomic testing is advancing so rapidly that the LCD list may not be up to date. Rather than using LCDs, therefore, Noridian states that it will use FDA labeling and "medical reasonableness" to guide its reimbursement decisions on genomic tests for now.

Unfortunately, most Medicare contractors have even less information about genomic testing reimbursement on their websites than Noridian, making it impossible to easily assess whether a personalized medicine test will be covered at a particular time for a particular patient.

Coding. If payer policies for coverage of personalized medicine tests are ambiguous, its coding system for them is vestigial, with most tests coded on insurance claims forms as a series of molecular steps (e.g., "PCR amplification x 10") or even more vaguely ("other clinical chemistry test"). That's because Medicare uses a clinical laboratory fee schedule dating back to 1984, which provides generic-rate reimbursement for molecular chemistry. The schedule is difficult or impossible to reconcile with the rising standards of clinical trial evidence for test coverage. As a result, payment for personalized medicine is archaic and often inadequate.

We hope the coming decade will see the establishment of more precise coding and coverage and more rational payment for personalized medicine tests under Medicare. These changes, which could be adapted for the private insurance industry, are a prerequisite for the success of personalized medicine.

The views expressed in this article are the views of the authors and do not necessarily represent those of the Personalized Medicine Coalition.

Pharma Explores New Business Model for Targeted Therapeutics

Pharmaceutical companies that have long been focused on developing blockbuster, one-size-fits-all drugs are adopting a new business model: developing a drug in tandem with a diagnostic test that identifies a subgroup of the patients who benefit from it, a hallmark of personalized medicine.

In a sign of the changing times, Pfizer, the world's top-selling drug company, has signed a deal with Abbott Molecular, the diagnostic arm of **Abbott Laboratories**, on a companion drug-diagnostic test that will guide clinical trials of a new cancer treatment. It is among the most recent and largest of similar agreements drugmakers have made with diagnostic companies in increasing numbers over the past few years.

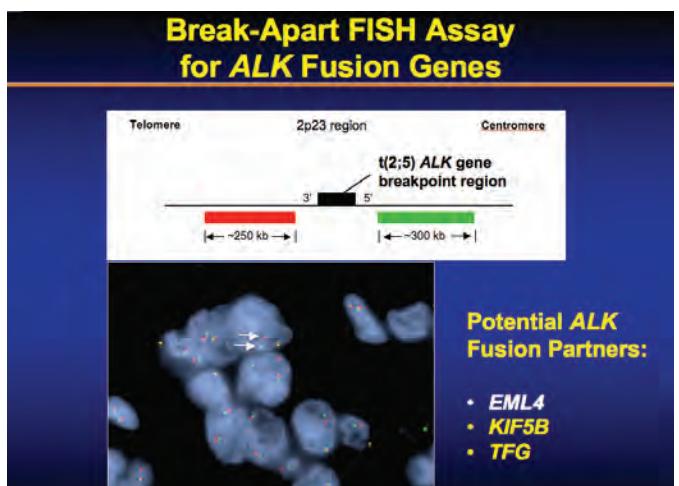
"The thinking has shifted," said Hakan Sakul, Ph.D., senior director of molecular profiling at **Pfizer Global Research & Development**.

Five or six years ago, Mr. Sakul said, he might have had trouble persuading some colleagues of the value of collaborating with diagnostic companies. Now, Pfizer has several in clinical development and in the pipeline, and one already on the market: the HIV drug Selzentry (maraviroc), whose FDA label recommends doctors establish the tropism status of their patients through a diagnostic test prior to administering the drug.

"There's a real convergence of interests now," said Alison

Ayers, vice president for commercial development oncology at Pfizer. "Payers are saying that they're not going to pay for 100 percent of people to take a drug if it only works for 20 percent of them. Everybody is going to have to get on board with this new scientific approach. We owe it to patients to identify the right drug for them, that will give them the best chance for improved survival."

For drug companies like Pfizer,



Targeted Medicine: The above assay shows the target for Pfizer's new cancer drug. A translocation on chromosome 2 has resulted in the formation of a fusion gene that includes parts of the echinoderm microtubule-associated protein-like 4 (EML4) gene and the anaplastic lymphoma kinase (ALK) gene in non-small-cell lung cancer (NSCLC) cells.

the new partnerships are a way to improve the chance that an expensive biotechnology drug will survive clinical trials and be adopted by the medical community. As more clinical trials now include early biomarker tests for toxicity or efficacy screening, it's become easier to develop the companion tests. The Food and Drug Administration's Office of Companion Products reports that there were 333 applications for combination products in fiscal 2007, 42 percent more than in the previous year.

Other recent collaborations abound. DxS partnered with **Amgen** in 2008 to develop a KRAS companion diagnostic test kit for Amgen's drug Vectibix. Merck and **Celera** last year signed an agreement for Celera to develop

biomarker and genetic tests based on gene expression profiles identified by Merck. Merck and Asuragen are collaborating on a gene-expression-based companion diagnostic for clinical trials for another cancer drug. Abbott last year announced a major partnership with **GlaxoSmithKline** on another lung-cancer drug. Abbott will screen non-small cell lung cancer tumors for expression of the MAGE-A3 antigen.

For Abbott, which has also formed partnerships with Astra Zeneca and Genentech, the rise in such deals is the result of exponential advances in the science of pharmacogenomics, says Stafford O'Kelly, president



Finding the target: The Abbott m2000 system, an automated instrument for DNA and RNA testing in molecular laboratories, is being used to identify the target for GlaxoSmithKline's new lung cancer drug. The system consists of two instruments, m2000sp for the automated purification of nucleic acids, and m2000rt for amplification and detection using real-time polymerase chain technology.

of Abbott Molecular.

"We've been talking about personalized medicine for 10 to 15 years, but real progress has been limited in terms of the impact on patient care," said Mr. O'Kelly. "However, increased biomarker discoveries and an improved understanding of how these biomarkers impact response to a therapy or side effects of a therapy are resulting in accelerated efforts in personalized medicine and companion diagnostics development."

Some three-quarters of all biomarker patent applications have been filed in the past three years, he said.

Abbott's test will determine which patients will benefit from Pfizer's new lung cancer drug, currently known as PF-02341066. The Abbott test will determine the presence of rearranged genes in the tissue of non-small cell lung cancer tumors, the most common type of lung cancer. Approximately 5 percent of patients with these tumors have the rearrangement resulting in

over-expression of a chimeric protein and will be candidates for a clinical trial of PF-02341066, which selectively inhibits the activity of the highly expressed gene. Gene rearrangement, a process that can help turn a normal cell into a cancerous one, is found in a wide array of cancers.

Lung cancer is the leading cause of cancer death in the United States, and the second leading cause of death after heart disease.

Right now, oncology is the "sweet spot" for drug/diagnostic partnerships, Mr. O'Kelly said, because of the heterogeneity of the disease and differences in patient response to therapy. The next area of medicine to benefit from targeted therapies will be neuroscience, he predicts. The science in that area is advancing by leaps and bounds. Cardiology is another area likely to see a sharp increase in drug/diagnostic combinations, he said.

But if the drug/diagnostic model has been adopted, it has not yet been

perfected, some diagnostic makers say. There are still a few kinks to be worked out, such as persuading more drug companies to join forces with diagnostic companies early in drug development even when it is not clear how the partners will share value, the consequence of different business models employed by each.

"Pharma companies are starting to explore those opportunities more often, but it's important for them to work with diagnostic early in the process," says Andrew Grupe, Ph.D., senior director of pharmacogenomics and director of central nervous system discovery research at Celera. "They need to keep in mind that it takes time to develop an IVD product, which they may need at the same time they get FDA approval. In the end everybody will benefit from a joint regulatory plan and synchronized timeline for both the drug and the diagnostic device."

Personalized Medicine Coalition Announces Two New Board Members

Appointments Deepen Expertise in Academia, Community Health

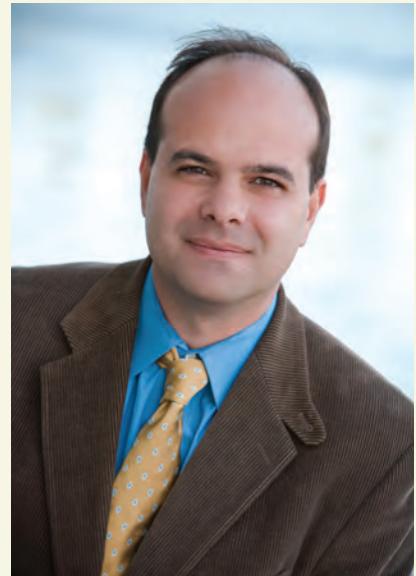
The Personalized Medicine Coalition (PMC) has appointed Clay Marsh, M.D., Director of the Center for Critical Care, **The Ohio State University Medical Center**, and Dietrich Stephan, Ph.D., Founder and CEO of the **Ignite Institute**, to its Board of Directors.

“Clay Marsh is not only a noted scientist and physician, but is leading the way in putting personalized medicine into clinical practice,” said Wayne Rosenkrans, PMC’s chairman. “Dietrich Stephan is a widely recognized visionary in molecular medicine who helped develop diagnostic tests and therapies for many different subtypes of common diseases and is a leader in the field of ‘translational medicine.’ The addition of both these distinguished scientists to our board will expand our ability to help providers and the public make personalized medicine a greater part of health care.”

Dr. Marsh, senior associate vice president for research in the Office of Health Sciences and vice dean for research in the College of Medicine, leads the planning and growth of Ohio State University Medical Center’s research programs. He led the effort to make the Medical Center a national leader in personalized health care.

“I am very excited to be more closely involved with the PMC to join its efforts to transform medicine,” Dr. Marsh said. “Our opportunities to improve health care delivery and offer more precise and personalized medicine are at an unprecedented level. However, to realize the great potential of leveraging advances in genetics, genomics and systems approaches to health care, we will need to fundamentally change our health care system, including reimbursement to providers, improving access to health care and transitioning our longitudinal health care focus from disease to health. The PMC is ideally positioned to facilitate the needed changes in policy, ethics, law and culture that will accelerate advancing personalized health care to our citizens.”

Dr. Marsh earned his medical degree from West Virginia State University and completed his residency in internal medicine at Ohio State, where he served as chief resident. He joined the Ohio State faculty in 1993 and holds appointments in four academic departments. His research, funded since 1991, currently focuses on the mechanisms underlying mononuclear phagocyte-induced inflammation.



Clay Marsh, M.D.; Dietrich Stephan, Ph.D.

He heads the Ohio State University for Personalized Health Care, which incorporates knowledge of an individual’s genetic information as well as environmental, behavioral and cultural factors into clinical practice to improve patient care.

Dr. Stephan founded the Ignite Institute this year in an effort to change the medical paradigm from reactive and generalized to proactive and personalized through the implementation of molecularly informed, tactical solutions. He has founded a number of companies, including Navigenics, Amnestix, and Aeuon, Inc. He served as Senior Investigator and Founding Chairman of the Department of Neurogenomics at the Translational Genomics Research Institute (TGen) in Phoenix, Ariz., and later moved into the role of Deputy Director of Discovery Research.

“This is a critical time in personalized medicine,” Dr. Stephan said. “It is a privilege to work with the PMC to address current issues in the personalized medicine space. By addressing these issues at the policy level, I think we will see a more robust health care ecosystem in which personalized medicine can thrive.”

Dr. Stephan has held faculty appointments at Johns Hopkins University, **George Washington University** and the University of Arizona. He received a B.S. in Biology/Biochemistry from Carnegie Mellon University and a Ph.D. in Human Molecular Genetics from the University of Pittsburgh Medical Center. He has completed a fellowship at the National Human Genome Research Institute.

Personalized Medicine: Right Here, Right Now

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can improve warfarin dosing. Warfarin is the second most widely prescribed drug in the United States and also, according to FDA, the second leading cause, after insulin, of drug-related emergency room visits.

CVS Caremark, a pharmacy benefit manager for 50 million subscribers, is partnering with **Generation Health**, a new genetic testing health benefit management company, said Troyen A. Brennan, M.D., CVS Caremark's Executive Vice President and Chief Medical Officer. Generation Health will analyze more than a dozen drugs with associated diagnostic tests to determine the best prescriptions for patients with cardiovascular disease, cancer and HIV and other diseases, according to Per Lofberg, president of CVS's pharmacy benefit management business.

DNA Direct, which provides guidance and decision support for genomic medicine, is partnering with **Humana**, an insurance company that covers 11 million people, on a program to teach doctors how genetic counseling can assure better outcomes and avoid unnecessary expenses, said Ryan Phelan, founder and CEO of DNA Direct.

Personalized medicine has been criticized as expensive, but Jerel Davis, Ph.D., engagement manager of management consulting firm McKinsey & Company, challenged that argument with research showing that it could potentially save

huge sums. Adverse drug events create an additional \$45 to \$135 billion per year in costs, he said; about a quarter of that expense could be averted through the use of diagnostic tests for appropriate biomarkers. And, of the \$292 billion spent on medications in 2008, about \$145 billion went for drugs that were ineffective for the patients who took them, he said.

The problem for personalized medicine isn't its cost but the fact that payers don't have evidence of cost efficacy, he said. In addition, providers are reimbursed based on how many procedures they conduct, not on the effectiveness of a particular treatment, he said.

A highlight of the conference was PMC's presentation of its 2009 Leadership in Personalized Medicine Award to Brook Byers, a managing partner in the venture capital firm **Kleiner Perkins Caufield & Byers** for his visionary activities to change healthcare and improve the lives of patients. M. Kathleen Behrens, Ph.D., a member of the Friends of the Personalized Medicine Coalition and founder of the KEW Group, presented the award, and Mr. Byers described his vision of the future of personalized medicine (see speech excerpt on page 12).

Presentations and photos from the conference, co-hosted by Partners HealthCare Center for Personalized Genetic Medicine and the Harvard Business School are available at www.personalizedmedicineconference.org.



JUSTIN KNIGHT, ALL

From left: Felix Frueh, Ph.D., describes how Medco offers molecular diagnostics to clients; Richard Hamermesh, D.B.A., leads a case study discussion on the business strategies behind colon cancer drugs Erbitux and Vectibix; David King, president and CEO of LabCorp, talks about how business can accelerate the development of personalized medicine.

Regulatory, Reimbursement Issues Remain for Personalized Medicine, Byers Says

Following is an excerpt from an acceptance speech by Brook Byers, a managing partner in the venture capital firm Kleiner Perkins Caufield & Byers, for PMC's "Leadership in Personalized Medicine" award.

I accept this honor on behalf of all the "Innovators" out there working to develop and offer the personalized medicine paradigm through diagnostics, drug/diagnostic combinations, devices and services. Personalized medicine is one of the best ways to improve quality and efficiency in healthcare, and reduce costs.

When I visualize "personalized medicine", I see...

...A heart transplant patient worries with his transplant surgeon that his body may be rejecting the new organ. Should they step up anti-rejection drug dosage, risking opportunistic infections and even cancer? Should another invasive biopsy be done, threading a catheter down the carotid artery to the new heart and literally "taking a piece"? They decide on a blood test to detect rejection before tissue damage is done. The test analyzes two dozen genes via rt-PCR with an algorithm and reports a score. Patients love it. Doctors love it.

...A primary care physician with a typical 1000+ patient workload worries about which of those he should focus on regarding risk of developing Type II diabetes. He decides to run a blood test to analyze seven proteomic factors correlated with risk of assessment of developing Type II diabetes within five years. This allows him to focus his attention, guidance, and even to prescribe low dose drug regimens to the 10 percent of his patients who are truly at significant risk while there is still time to prevent diabetes from happening. Patients love it. Doctors love it.

...And I visualize dozens and dozens more real tests in development to determine things like the 50 percent of patients who will (or will not) benefit from biologics or drugs (many of which are costly); detect kidney failure long before creatinine levels rise; know who will benefit (or not) from an implanted defibrillator (which is invasive and high cost); and coming applications from new imaging techniques and from rapid, low cost sequencing of the human transcriptome...

The personalized medicine tests I visualize are real (I am involved in many of them) but the helpful cooperation that Innovators need from government authorities and payers, sadly, is not yet there.

The greatest enemy for Innovator Entrepreneurs, whether in new ventures or big organizations, is time. Time eats away at funding as "burn rate." Time saps motivation for change.



Brook Byers

JUSTIN KNIGHT

Time leaves more patients behind, especially those who do not have time to wait.

Innovators know to "put the key risks up front" and eliminate them. But the irony today is that after the Innovators in personalized medicine overcome the risks of scientific breakthroughs and product development and clinical trials and peer review publications, more risks await them in regulation and reimbursement.

The Innovators in personalized medicine often feel that regulators and payers take for granted that substantial investments in personalized medicine will continue despite these obstacles. Innovators in personalized medicine also find that the cost savings potential of personalized medicine is underappreciated.

The irony of the current regulatory and reimbursement systems is that these create much uncertainty for innovators and can unintentionally hurt the kinds of innovation necessary for true health care reform. These innovations include tests involving new molecular methods that have been shown to be scientifically and clinically superior to older methods. They are improving the overall quality and efficiency in healthcare and, in many cases, reducing costs.

In addition, our therapeutic-centric mentality of health care should shift to give more emphasis to diagnostics.

The Innovators are doing their part for personalized medicine. They are spending on average three years and tens of millions of dollars to develop and rigorously validate each new product, amounts that represent massive increases in R&D expenditures for diagnostic tests.

Here is a thought experiment: where is the federal stimulus money for personalized medicine? Where is the federal non-monetary help for these Innovators?

Thankfully, there are effective organizations advocating repairing the regulatory and reimbursement impediments to personalized medicine. If you haven't already done so, I encourage you to join both the Coalition for 21st Century Medicine and the Personalized Medicine Coalition.

Teams win. I still dream of getting Innovators, regulators, payers, legislators, and the Administration onto one team.

A great way to achieve the populist ideal of every person receiving the best possible care is through widespread personalized medicine.

Those patients I describe worrying with their doctors aren't a dream, they are living with an everyday harsh reality.

The time for personalized medicine is now.

These comments are personal observations by Mr. Byers and do not reflect product claims by manufacturers or laboratories.

PMC Greets New Members, Old Friends

BOSTON — The Personalized Medicine Coalition reached out to new members and welcomed old friends at its reception attended by nearly 200 guests at the Hotel Commonwealth on November 17, on the eve of the fifth annual personalized-medicine conference at Harvard Medical School.

The event was highlighted by speeches from pioneers in the field of personalized medicine, including PMC's founder, Brian Munroe, who received an award recognizing his dedicated service to the Coalition. Munroe, vice president of government affairs at **Endo Pharmaceuticals**, founded the organization in 2004 with fewer than 20 members.

"Brian Munroe is someone who understands that what we are doing is hard, disruptive, important and requires constant commitment," said

Edward Abrahams, PMC's executive director. "He understands how to create a powerful organization in Washington whose sum is larger than its parts. He is someone who understands that timing is critical; someone who understands, as Shakespeare wrote, that 'There is a tide in the affairs of men, which, taken at the flood, leads on to fortune.'"

In accepting the award, Munroe said many individuals were essential to the growing success of the Coalition, and praised PMC's legislative achievements.

Also speaking at the reception was Raju Kucherlapati, Ph.D., whom Abrahams described as a "scientist, entrepreneur, and visionary." Dr. Kucherlapati talked about how much has been achieved in the field since he created the first personalized-medicine conference at Harvard Medical School

five years ago. (Please see page 1 for an article on the conference.) Dr. Kucherlapati is Paul C. Cabot Professor of Genetics at Harvard Medical School.

In addition, venture capitalist Mark Levin, the managing partner of **Third Rock Ventures** and former CEO of **Millennium Pharmaceuticals**, looked back at the way personalized medicine has emerged as a growing factor in health care in recent years.

The reception also featured an animated presentation of Milestones in Personalized Medicine by PMC, which was created by Feinstein/Kean Healthcare. The presentation will be available soon at www.personalizedmedicinecoalition.org.

Feinstein/Kean Healthcare, L.E.K. Consulting, and *Personalized Medicine* sponsored the reception.



RICK FRIEDMAN

Brian Munroe, PMC's founder, accepts an award for his dedicated service to the Coalition.

FROM THE EXECUTIVE DIRECTOR

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that our education and advocacy efforts on behalf of good science and good medicine are having an impact. We have come a long way since fewer than twenty institutions launched the PMC at the end of 2004.

Although Representative Schrader, recognizing that the Senate's bill incorporated his concern that we not lock medicine into a one-size-fits-all paradigm, later withdrew his amendment to help ensure final passage of the measure, he did get the House Leadership's attention. Both he and they recognized the importance of supporting the principles of personalized medicine.

When, five years ago, we launched the PMC to create a friendlier environment for the development and adoption of personalized medicine, few Members of Congress had an inkling of what personalized medicine was and half of those got it wrong. Although many still fear that personalized medicine could raise the cost of healthcare, not lower it as we contend, today there is a widespread understanding of personalized medicine: what it is, why it is important, and what the government can do to help advance it, thanks in large part to our work.

As this newsletter goes to press, PMC is on the brink of a major victory, having secured a legislative beachhead for personalized medicine in healthcare reform legislation. This will serve us well when we focus attention on regulation and reimbursement next year.

If our work on CER was the most dramatic example of PMC's success in 2009, there were others as well.

Chief among these was our continued growth as an organization, the necessary condition to support our educational and advocacy efforts.

I am pleased to report that the Coalition increased in size by 14 percent last year, from 143 members to 163 in a year that was financially challenging for many institutions due to the worst recession since the 1930s. Forty-nine new members joined the PMC in

2009, though 29 did not renew. Our members represent all the healthcare sectors with an interest in advancing personalized medicine. (For a list of PMC's membership, see page 6 with new members noted in *italics*.)

Our 2009 revenues are also projected to rise from \$1.2 million to \$1.6 million, or 40 percent, an increase that allowed us to organize conferences, lobby Congress, and write a white paper for FDA, highlights of the year. In addition, PMC has added over \$200,000 to its net assets, bringing the organization closer to its goal of six months cash reserves, the sign of a fiscally healthy non-profit educational institution, and up from zero five years ago.

Looking ahead, PMC is working with key senators and members of Congress on the re-introduction of the Genomics and Personalized Medicine Act; the implementation of CER at the agency level; regulatory issues at FDA, notably companion diagnostics; developing a strategy to advance value-based reimbursement for diagnostics; publishing a white paper on

Health Information Technology and personalized medicine; on physician education regarding developments in personalized medicine in areas outside of oncology such as cardiology and diabetes; and on increasing our presence and outreach in Europe.

To kick off the year, PMC's guest speaker at its Sixth Annual State of Personalized Medicine Luncheon at the National Press Club in Washington, D.C. will be FDA Commissioner, Margaret Hamburg, M.D. We hope you will attend. Sponsored by the Friends of the Personalized Medicine Coalition, it is scheduled for February 25th at noon. As always, there will be no charge for PMC members.

None of this would be possible without your commitment. We count on your membership renewal in 2010 so that we can continue to advance PMC's goals. Your support is crucial if we are going to change the landscape of healthcare in ways that we know will serve the interests of patients.



Improve the Quality and Affordability of Health Care

Support H.R. 2502, the Comparative Effectiveness Research Act of 2009
Endorsed by over 100 groups representing patients, providers, people with disabilities, minority communities, & researchers.

Dear Colleague:

As healthcare reform legislation moves forward, it is essential that comparative effectiveness research be included. We also need to ensure such research is focused on patient needs and grounded in sound science. That is why I intend to offer HR 2502, the Comparative Effectiveness Research Act of 2009, as an amendment during next week's Rules Committee consideration of the Affordable Health Care for America Act. This bipartisan legislation is supported by over 60 Members of the House of Representatives and I urge you to join as a cosponsor in advance of the Rules Committee consideration process.

While the current comparative effectiveness language in the House legislation was changed to reflect some of the principles in HR 2502, it fails to reinforce the core tenet of healthcare – that **patients and doctors should be making medical decisions, not insurance companies or large employers**. By advancing the conduct and communication of research on patient health outcomes, HR 2502 gives patients and consumers the information they need to make good medical choices, without dictating those choices. It also ensures a role for the federal government in improving the quality and efficiency of healthcare by encouraging efficiencies and value,

PMC Urges FDA to Clarify Rules for Drug-Diagnostic Combinations

In an effort to encourage medical care that takes account of molecular differences among patients, the Personalized Medicine Coalition has written the Food and Drug Administration (FDA) urging the agency to clarify its requirements for approving drug-diagnostic combinations.

At issue are combinations of targeted drugs and molecular diagnostics, the hallmark of personalized medicine. Companion diagnostics can target therapy more precisely by identifying potential responders or non-responders to a specific drug, and by more precisely identifying individuals at risk for adverse events.

Although companion diagnostics could substantially improve the accuracy of medical care, they've been slow to take off, in part because FDA has failed to follow up on a "concept" paper it published in 2005 on how the drug/diagnostic combinations might be regulated. Drug and diagnostic makers have been left in limbo on how the government will treat new products, even as the science to develop more innovative diagnostic tests and targeted drug therapies has sped forward.

"People have been clamoring for guidance from FDA on this issue," said Robert E. Yocher, Vice President for Regulatory Affairs at

Genzyme Corporation, who led the PMC working group that drafted the comments. "We felt it was important to help speed the process by our ability to reconcile differing views."

A total of 40 PMC members primarily from the laboratory, drug and diagnostics sectors served on the working group that developed PMC's comment letter, which Sheila Walcoff and Paul Radensky, M.D. of **McDermott Will & Emery LLP** revised and finalized for submission to FDA.

"By bringing together the three communities most impacted by FDA action on the regulation of companion diagnostics—diagnostic kit manufacturers, pharmaceutical companies and laboratories—to create a consensus document, PMC provided the agency with unique insight," said Amy Miller, PMC's public policy director.

Unless FDA can establish clear, consistent regulations

for co-developed and companion drugs and diagnostics, personalized medicine will not thrive and its promise to improve health and reduce inefficiency in the health care system will not be realized, the Coalition wrote in its 14-page comment letter.

"Although genomic science and technology continue to advance rapidly, the ability of innovative companies to co-develop, validate and commercialize drugs and

diagnostics cannot realize its full potential for the benefit of patients without greater regulatory clarity, in particular with respect to the standards of evidence necessary to validate co-developed and independently developed diagnostics to support a specific reference to or requirement for such testing in therapeutic labeling as well as the process developers should take to develop such evidence," PMC wrote.

Without explicit rules, physicians and patients lack a clear understanding of which diagnostics FDA has approved, PMC said, and companies must navigate multiple centers and divisions at the agency to obtain approval for their products.

FDA Commissioner Margaret Hamburg has said that FDA's current "regulatory schemas" are ill-suited for genetic and genomic testing and the broader field of personalized medicine. She has said that the FDA is

"on the cusp of a whole new way of doing business" with respect to when and how it will regulate the building blocks of personalized medicine such as genetic tests and targeted drug therapies.

A copy of PMC's letter to FDA is available at www.personalizedmedicinecoalition.org.



Above: Robert E. Yocher, who led PMC's development of FDA comments. Below: The PMC Public Policy and Clinical Science Committees review PMC's comment letter to FDA on drug-diagnostic combinations.

PMC IN THE PRESS

GenomeWeb reported in December that the Personalized Medicine Coalition (PMC) said in comments to the Food and Drug Administration that drug/diagnostic co-development may not be a single test developed simultaneously with a single drug, as FDA envisioned in its 2005 concept paper. PMC argues in its comments that future guidelines on drug/diagnostic co-development must delineate areas of regulatory flexibility and address alternative development models to account for the variety of real-world challenges companies face. Articles on the comment letter were also filed by **Inside Health Policy**, **FDA Week** and **Pharmawire**.

In a December article on federal stimulus money for personalized medicine, **In Vivo: The Business and Medicine Report** quoted Brook Byers' speech accepting the Leadership in Personalized Medicine Award from the Personalized Medicine Coalition. In addition to Byers, a partner with VC firm Kleiner Perkins Caufield & Byers, the magazine interviewed PMC Board members Felix Frueh, Vice President for Personalized Medicine Research and Development at **Medco**, Mara Aspinall, president and CEO of **On-Q-ity**, and Pierre Cassigneul, president and CEO of **XDx**.

Reuter's reported in December that tailoring medicine to a person's genetic makeup is poised to bear fruit in a major way in the next few years, thanks to companies like **Medco**, which is investing in clinical studies that examine the role of individual's genes and medicine in health outcomes. **Medco's** investment "is the single biggest development in bringing personalized medicine to broad sections of the population," said Edward Abrahams, executive director of the Personalized Medicine Coalition.

The efforts of a healthcare industry coalition to stall implementation of certain aspects of the Genetic Information Non-Discrimination Act have personalized healthcare stakeholders worried, **Genome Web** wrote in December. "One of the founding principles of the PMC is that individuals should not be discriminated against based on their genetic information," said Amy Miller, public policy director of the Personalized Medicine Coalition. "We support implementation of GINA as passed and signed into law."

The Scientist reported in December that pharmacogenomics may be able to bring some stalled drugs back to life, citing bucindolol and methotrexate as drugs that fell short of becoming blockbuster therapeutics but that may find niche application with the development of novel genetic tests. "If **Merck** could have known in advance who would have cardiovascular problems from **Vioxx**," said Edward Abrahams,

PMC's executive director, "they may not have had to withdraw it from the market."

The most sweeping federal anti-discrimination law in nearly 20 years has taken effect, prohibiting employers from hiring, firing or determining promotions based on genetic makeup, **The Los Angeles Times** reported in November. In addition, health insurers will not be allowed to consider a person's genetics to set insurance rates or deny coverage. "The psychological security regarding employment and insurance was a stumbling block to the advancement of personalized medicine," said Edward Abrahams, PMC's executive director. "Moving that boulder from the train tracks was a major accomplishment."

Boston Globe reported in November that PMC Board Member Mara Aspinall is leading a new cancer diagnostics business, **On-Q-It**. The company recently raised \$21 million from venture capital investors. Diagnostics are "generating a lot of investment and a lot of excitement," PMC Executive Director Edward Abrahams told the paper, and are an emerging area for venture capitalists.



RPM Report reported in November that Janet Woodcock, director of FDA's Center for Drug Evaluation and Research, said that for comparative effectiveness research (CER) and genomic medicine to converge, the US must invest in its research infrastructure to conduct studies in real-world settings. Woodcock spoke at a conference co-hosted by the Personalized Medicine Coalition and the National Pharmaceutical Council. Reports on the conference were also filed by the **Pink Sheet**, **GenomeWeb**, **FDA Week**, and **Reuter's**.

Inside Health Policy reported in October that the House had tweaked its healthcare reform bill to include language that requires policymakers to take molecular and genetic differences into account when designing comparative effectiveness research. Although personalized medicine advocates sought bigger changes, the Personalized Medicine Coalition said the tweak is nevertheless "a drastic improvement."

The San Diego Union Tribune wrote in October about a new genetic test that identifies people who likely won't benefit from taking Plavix, a common anti-clotting drug, after having a stent placed in an artery. "This is significant news for medicine as well as health care costs," PMC Executive Director Edward Abrahams told the newspaper. "Getting it right the first time makes a lot of difference to people who suffer from blood clots."