

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.

FALL 2008

| Letter from the Executive Director



At a national summit on personalized healthcare held on October 5 in Park City, Utah, U.S. Secretary of Health and Human Services Michael O. Leavitt opened the conference by quoting Warren Buffett: "It's hard to tell who's swimming naked until the tide goes out."

With an eye on Wall Street, then seemingly in free fall, Secretary Leavitt said our healthcare system faces many challenges, including escalating costs, declining value, and a seeming inability to institute reforms that would improve delivery and contain costs. These, he said, could represent a second tsunami, after the banking crisis, that will rock the foundations of our society.

With a defining election impending on November 4, it became increasingly obvious to the 150 invited guests at the Utah conference, co-sponsored by PMC, that 2008 represents a caesura in time. Healthcare—including how it is accessed, regulated, and reimbursed—will be the subject of focused inquiry and potentially profound changes. The status quo that has existed since the creation of Medicare in 1965 is unlikely to remain untouched.

The challenge that PMC faces is to ensure that personalized medicine is not only part of the post-election debate over healthcare but also part of any proposed solutions. As we know from our ongoing work in the policy arena, the promise of personalized medicine is that it not only improves health but also that it may well do so at lower cost than conventional approaches. Preventive, coordinated, and evidence-based personalized medicine proposes to employ new discoveries regarding what works, for whom, and why, as well as more efficient new health information technologies, so that we might better control our healthcare system in the future.

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| Policy Brief

As we move into a new year with a new administration, it helps to reflect on PMC's main mission—overcoming barriers that obstruct the advancement of personalized medicine. Two conversations begun in 2008 will continue in 2009: the regulation of consumer genomics and the reimbursement of personalized-medicine products by both public and private payers.

The "buck" stops with those who pay for products. Payers are not yet sold on the value that personalized medicine products can bring to the healthcare system. Consumer genomics serves personalized medicine by bringing awareness of personalized-medicine concepts and products to the general public, yet it poses the familiar danger of overpromising, with members of the public expecting benefits that as yet can be delivered only some of the time.

During federal deliberations in 2008, it became apparent that the consumer genomics industry was attracting attention from regulators as well as from many constituencies within personalized medicine. Since then, PMC has convened industry leaders and interested partners to discuss and seek to develop voluntary standards for this new industry. The group has begun work on scientific standards underlying consumer genomics products and is expected to produce a report before the end of the year. Federal regulators are aware of these voluntary industry efforts, but their attention has not waned. Concerned with protecting consumers against inappropriate medical testing, the Centers for Disease Control and Prevention will be hosting a conference here in Washington, D.C., on Dec. 17-18.

In 2008, the PMC has focused in large part on the FDA. We had frequent conversations with FDA

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| Analysis: Report Calls for Greater Federal Support of Personalized Medicine

When President-elect Barack Obama assumes the responsibilities of the American presidency on January 20, he will confront enormous challenges, including a troubled economy, global warming, and the developed world's dependence on unstable supplies of oil. Not least among those challenges is the rising cost of healthcare, which has been a major focus of the just completed campaign. Unless these issues are resolved, the people of the United States, as well as other nations, will find that our world will become poorer, meaner, and less healthy.

Fortunately, we are in an era where old answers have been found wanting. There is receptivity to trying big, bold new approaches based on paradigm changing advances in science and technology. One of those approaches is what we call personalized medicine—the idea that linking drug discovery, development, and delivery to our emerging understanding of molecular diagnostics, mediated by powerful health information technologies, can improve health and lower overall costs.

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This is the vision, and there are reasons to be optimistic that we will achieve it.

First, Secretary Leavitt, by underlining the potential of personalized healthcare, has prepared the groundwork for future initiatives.

Second, the outline of an educational and policy platform focusing on tools, regulation, and reimbursement has been built, the latest example of which is the new report of the President's Council of Advisors on Science and Technology (PCAST), *Priorities for Personalized Medicine*. (See page 1)

Third, a number of institutions around the country have announced their commitment to putting the paradigm of personalized medicine into practice where possible. These include Baylor University, Brown University, Children's Hospital and Research Center Oakland, Cincinnati Children's Hospital Medical Center, Georgetown University, George Washington University, Cleveland Clinic, Duke University, Harvard University, Marshfield Clinic, Mayo Clinic, National Jewish Medical and Research Center, The Ohio State University, the University of Pennsylvania, University of Medicine and

Dentistry of New Jersey, University of Utah, and Vanderbilt University, to name only a few. The day after the Utah conference, Governor Jim Doyle of Wisconsin announced an initiative "to make Wisconsin a worldwide leader in personalized medicine."

With over 150 members from across the entire healthcare spectrum and high credibility among Washington policymakers, PMC is positioned to be the voice for personalized medicine in 2009. We have activities planned in coming months to enhance our ongoing educational work in the halls of government and among members of the public, including a conference scheduled for January 27 on the return on investment in targeted therapeutics. (See page 5) In partnership with the Deloitte Center for Health Solutions, we will unveil an important study that examines the critical issue of how to drive investment among pharmaceutical companies, diagnostic firms, and payers in personalized medicine, each of which, suffice it to say, approaches the challenge from a different perspective.

In addition, under the direction of PMC's Public Policy Director, Amy Miller, the Coalition has proactively sought to open a conversation with the Centers for Medicare

and Medicaid Services (CMS) whereby personalized medicine products will receive favorable review, to support the U.S. Food and Drug Administration's (FDA's) ongoing efforts to create a more favorable regulatory framework for diagnostic products, and to work with Evaluation of Genomic Applications in Practice and Prevention (EGAPP) to consider alternative pathways to demonstrate clinical utility. PMC also is working with consumer genomics companies to better understand and perhaps guide their entry into this new marketplace.

As we go into this new era, we ask you not only to renew your institutional membership in PMC but also to become a "catalyst" member in recognition of the challenges and opportunities we are witnessing. A "catalyst" member voluntarily agrees to increase its membership payment by fifty percent and to be recognized as a sponsor of our fifth annual kick-off address on the state of personalized medicine at the National Press Club on March 3, when our guest speaker will be Denis A. Cortese, M.D., President and CEO of the Mayo Clinic. ■

— Edward Abrahams, Executive Director
Personalized Medicine Coalition

| Policy Brief *continued from page 1*

regulators and leaders and have been pleased to see that, over this period, the FDA has moved our agenda forward by relabeling warfarin and abacavir to recommend genetic testing before beginning therapy. However, the success of a commercially available product depends on finding someone to pay for it. In healthcare, that means convincing private and public payers that personalized medicine products are worth covering.

This year, CMS opened a national coverage determination (NCD) for warfarin diagnostics and proposed a list of future NCDs, two of which were related to personalized medicine. An NCD is the process by which the government decides whether or not to pay for a healthcare product. The comments that CMS has received on its pending warfarin decision reflect the many different perspectives among stakeholders and among PMC's members. PMC's own response to CMS, posted on our Web site, articulates the problem. In brief, the issues are what constitutes appropriate evidence for personalized medicine products and what

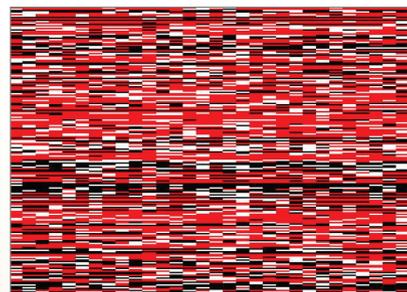
will satisfy payers. Arguably, expensive randomized clinical trials are not appropriate for personalized medicine diagnostics because the sophisticated diagnostic tests are not reimbursed sufficiently to cover their costs, evolve over time, and inform treatment decisions.

We are at the beginning of this important discussion. Publicly debating the different perspectives will allow us to find common ground and build upon it. This debate represents another opportunity for PMC to deliver on its promise to convene thought leaders in a constructive effort to develop solutions to the problems that prevent personalized medicine from becoming the new standard in healthcare.

As we move into 2009, the debate over reforming our healthcare system will garner a lot of attention. PMC will work with legislators and federal officials to make sure that these efforts recognize personalized medicine as an improvement over current practices and seek to ensure that any reforms

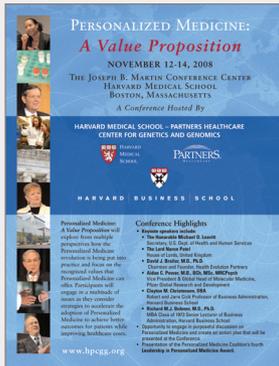
that become law also reward innovation upon which patients depend. ■

— Amy M. Miller, Public Policy Director
Personalized Medicine Coalition



"DNA Collage 1," created by PMC Board member Gualberto Rúaño, M.D., is a "snapshot" of variations in the genome sequences of 62 people, one to a column, from blood samples taken in clinical studies at Hartford Hospital, where Rúaño is Director of genetics research.

Leading Officials to Discuss Value of Personalized Medicine



Top policymakers, business officials, and academic experts in business and science will gather to discuss the ways in which they can advance the implementation of personalized medicine at a conference in Boston, Mass. on November 12–14.

The conference, *Personalized Medicine: A Value Proposition*, is co-hosted by the Harvard Medical School-Partners HealthCare Center for Genetics and Genomics and Harvard Business School, in collaboration with PMC. It will examine

the political, economic, and scientific issues that affect the adoption of personalized medicine. Participants will identify and consider ways in which the medical and business communities must work together to make personalized medicine the common standard for patient care.

“This is an important forum for a rich exchange of ideas about the value of personalized medicine,” says Raju Kucherlapati, Ph.D., of Harvard Medical School, Chair of the conference organizing committee.

A special feature of this year’s conference will be a symposium on November 12 that will focus on the essential role of information technology in the implementation of personalized medicine.

Key topics at the conference also include:

- How clinical trials and scientific discovery are demonstrating the value of personalized medicine;
- How genetics can be incorporated into the healthcare system;
- The business outlook for integrating genetics and genomics as health information tools;
- Information technology in personalized medicine; and
- What value-based purchasing and reimbursement for personalized medicine products might look like in the future.

Among those speaking will be Michael O. Leavitt, HHS Secretary; David J. Brailer, M.D., Ph.D., Founder of Health Evolution Partners and former National Coordinator for health information at the U.S. Department of Health and Human Services; Clayton M. Christensen and Richard M.J. Bohmer, both Professors at Harvard Business School; and PMC Board members Mara G. Aspinall, Senior Advisor, **Genzyme Corporation**; Felix Frueh, Ph.D., Vice President of research and development for personalized medicine, **Medco Health Solutions**; and David King, President of the **Laboratory Corporation of America (LabCorp)**.

A highlight of the conference will be the Coalition’s annual 2008 Leadership in Personalized Medicine Award from the PMC. The annual PMC award recognizes the contributions of a visionary individual whose actions in science, business, or policy have advanced the frontier of personalized medicine.

The conference will be held Nov. 12–14 at the Joseph B. Martin Conference Center, Harvard Medical School, 77 Avenue Louis Pasteur, Boston, Mass. PMC members will receive a discounted rate for the conference. For more information or to register, visit the conference Web site at <http://www.hpcgg.org/PM/2008/index.jsp>. ■

Public Policy Speaker Series: Dora Hughes, M.D.

Under a Barack Obama administration, much of the work begun by U.S. Health and Human Services Secretary Michael Leavitt on personalized healthcare would continue, and some of the provisions Senator Obama has proposed to support personalized medicine in the Senate could be enacted by executive order, according to Dora Hughes, M.D., Health Advisor to the Illinois Democrat.

Hughes, who spoke with the Personalized Medicine Coalition in July, said Senator Obama is committed to a broad increase in biomedical research funding and to retraining medical workers in the application of genetic information. She added that an Obama administration would improve the healthcare system in

part through personalized medicine, and that no options for stimulating its development are off the table, including patent exclusivity extensions for personalized medicine therapeutics. Many observers had assumed such a provision would be unacceptable in the current political environment.

Hughes said she was pleased that Representative Patrick Kennedy, Democrat of Rhode Island, had introduced a House version of Senator Obama’s Genomics and Personalized Medicine Act that also included incentives for businesses, an improvement suggested by the PMC. Other incentives to promote personalized medicine are possible, she said, but Senator Obama wants to reward only those innovations that actually improve healthcare.

Public Policy Speaker Series: Lawrence J. Lesko, Ph.D.

A top FDA official has asked PMC to propose regulations for products that combine a diagnostic test and a therapeutic treatment in one as a way to help the FDA write its own regulations, thus removing a barrier to the development of many personalized medicine products.

At a meeting with the Coalition in May, Lawrence J. Lesko, Ph.D., Director of the Office of Clinical Pharmacology, Center for Drug Evaluation Research (CDER), said PMC is unique because it has the active engagement of a wide range of key stakeholders in personalized medicine. Therefore, the FDA would take “very seriously” any guidance developed by PMC, he said.

Although the FDA published a white paper in 2005 on co-developed diagnostic-therapeutic products, it has

yet to propose formal guidance on them. The lack of regulatory certainty has had a chilling effect on the development of new products.

Lack of regulations aside, Lesko said the FDA has a good track record on personalized medicine. Relabeling warfarin to recommend diagnostic testing for sensitivity and metabolism genes before it is prescribed is only one of many actions the agency will take to support personalized medicine, he said. (Since the meeting, the FDA also has relabeled the HIV drug abacavir to recommend genetic testing before a patient starts or re-starts the drug and has renewed its commitment to producing formal guidance on co-developed products.) Few personalized medicine products are awaiting FDA review because review of targeted therapeutics is a priority for CDER, Lesko added.

Related Links:

- PMC abacavir press release: http://www.personalizedmedicinecoalition.org/communications/pr_2008-07-24.php
- FDA’s genomic biomarkers in drug labels: http://www.fda.gov/cder/genomics/genomic_biomarkers_table.htm

Co-developed Products:

- List of co-developed products from the FDA <http://www.fda.gov/CDer/genomics/pharmacoeconceptfn.pdf> ■

Report Calls for Greater Federal Support of Personalized Medicine

continued from page 1

When it comes to realizing the promise of personalized medicine, the new president will not be starting with a blank slate. Substantial bipartisan support for this vision has developed over the past few years, and observers outside the federal government have suggested ways the government can expedite development and adoption of personalized medicine. Now, many of those ideas have been endorsed, and others proposed, by a presidential advisory group.

In September, the President's Council of Advisors on Science and Technology (PCAST), a group of leading figures in the private sector who offer counsel on science policy in the United States, issued a little-heralded but important report, *Priorities for Personalized Medicine*. According to PCAST co-chairs John H. Marburger III, Director of President Bush's Office of Science and Technology Policy, and E. Floyd Kvamme, a partner in the venture capitalist firm **Kleiner Perkins Caufield & Byers** in Menlo Park, Calif., the promise of better health outcomes at lower systemic costs requires "the federal government [to] develop a strategic, long-term plan that coordinates public and private sector efforts to advance research and development relevant to personalized medicine."

Under the direction of PCAST member M. Kathleen Behrens, a general partner in RS & Co. Venture Partners IV, a venture capital fund in San Francisco, Calif., *Priorities for Personalized Medicine* outlines a strategy to realize the vision of personalized medicine. Building on the foundation that HHS Secretary Michael Leavitt put in place with his Personalized Health Care Initiative, the report focuses on three priorities: technology and tools, regulation, and reimbursement.

Technology and Tools

The report states that among the significant scientific roadblocks to widespread clinical adoption of genomics-based molecular diagnostics is the lack of follow-up research to validate genetic markers that have been identified by early research. Because the validation of genomic correlations with disease is a new, expensive, and high-risk research area, the government will need to work with the private sector to make sure the research is carried out, the report concludes.

In addition, the government needs to develop a long-term plan for public and private sector research and development, working with the private sector to create a public/private "Personalized Medicine R&D Roadmap" for coordinating discovery and translational research.

The report also recommends that government and industry join forces to create new tools that will facilitate further research: building a collection of high-quality biological specimens accompanied by comprehensive disease annotation, using standardized biomarkers and incorporating sophisticated statistical methods that can demonstrate the clinical validity of genomic profiles in studies, and assembling a large population cohort for longitudinal health and disease studies.

Regulation

While the FDA has made progress in developing regulations for genomics-based molecular diagnostics, the report says its guidance remains ambiguous or incomplete in several important areas. Among them:

- Developing criteria that define risk for products, including diagnostic tests, where information is the key result;
- Developing standards for study design and product performance with regard to regulatory review of new diagnostic products;
- Coordinating with CMS to ensure that the two federal agencies do not have redundant regulations for personalized medicine products;
- Setting standards for labeling therapeutic products that use diagnostics; and
- Deciding how to regulate computerized clinical decision systems.

The Critical Path Initiative launched by the FDA in 2004, which is designed to help smooth development of drugs and devices, has been hampered by inadequate funding, a situation that needs to be remedied, the report notes.

Finally, the private sector, the report recommends, needs to work proactively with the FDA on regulatory policy. Industry should respond "in a substantive and positive way" to requests for information and draft guidance released by the FDA by submitting alternatives "rather than primarily registering objections," the report says.

Reimbursement

The authors identify three key challenges to containing healthcare costs without obstructing the adoption of genomics-based molecular diagnostics. First, genomics-based molecular diagnostic tests are currently reimbursed at the same rate as other laboratory tests—in other words, as low-margin commodity items. Industry is unlikely to develop new products if it is unable to recover its development costs, according to the report.

Second, standards are lacking for the evidence that CMS and other payers will require to validate the benefits of these tests in practice.

Third, the procedural hurdles associated with coding systems, bundled payments, and complex billing procedures make it particularly difficult for patients to receive reimbursement for innovative molecular diagnostics and, therefore, to benefit from the promise personalized medicine represents.

For personalized medicine to develop, public and private payers should set reimbursement rates for genomics-based molecular diagnostics based on their overall impact on patient care, the report concludes. Payers also should help develop standards for clinical trial designs that they would accept as providing sufficient evidence to cover a particular diagnostic.

In addition, payers should collaborate with test developers to establish more flexible coding approaches for reimbursement. They should expand "coverage with evidence development" programs, which extend coverage and reimbursement while a product is being investigated, as a way of encouraging new product development, the report says.

The Personalized Medicine Coalition supports most, if not all, of the recommendations. We look forward to working with the new administration to put them in place, beginning with the report's final proposal, that the personalized medicine office that Secretary Leavitt created at HHS be made permanent.

A link to the report is available online at <http://ostp.gov/cs/pcast>. ■

Sign up

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

www.PersonalizedMedicineCoalition.org.

| Cortese to Speak on State of Personalized Medicine

Denis A. Cortese, M.D., President and CEO of the **Mayo Clinic**, will give the keynote address for PMC at its fifth annual forum on the state of personalized medicine on March 3, 2009 in Washington, D.C.

The annual address provides an opportunity to explore developments in the field of targeted therapeutics, giving PMC members and guests an opportunity to hear and engage in discussion with a leader in health policy about timely and important issues facing personalized medicine. Mayo Clinic is playing a pivotal role in the adoption of personalized medicine by incorporating pharmacogenomics into patient care. Pharmacogenomics, Cortese says, enables doctors to know ahead of time if the medication they are considering will help, harm, or have no effect on a patient.

According to Cortese, the Mayo Clinic aims to incorporate genomics into every aspect of patient care, including predicting and preventing disease, more precise diagnosis, and tailored treatment for individual patients.

“We know that effective treatment doesn’t mean ‘one size fits all,’” he says. “In the future, we’ll be able to customize your treatment plan and intervene at the earliest stages, even at the point of prevention. This will have a huge impact on quality of life for patients and cost savings for society.”

The address will be held from noon to 2 p.m. at the National Press Club, 529 14th Street, N.W., in Washington, D.C. For more information on the address, or to register, visit www.personalizedmedicinecoalition.org. ■

| PMC Conference to Examine ROI in Personalized Medicine

Where is the return on investment in personalized medicine? Leaders in business and policy will take up this question and others at a conference sponsored by PMC on January 27, 2009, in Washington, D.C.

Although it might be debated how quickly the new discoveries in molecular biology will transform healthcare, it is widely assumed that they point towards personalized approaches to drug discovery, development, and delivery. Less well understood, but no less important than the advances in science and technology that underpin personalized medicine, are the business models that will accelerate or slow the necessary investment to bring more effective and safer therapies to patients.

Unless pharmaceutical, diagnostic, and insurance executives can see returns on their investments in research and development, they will necessarily remain cautious, for example, about co-developing diagnostic and therapeutic products. External forces, including the precipitous decline of new blockbuster, one-size-fits-all drugs, increasing valuations for diagnostic products, and the escalating cost of healthcare, have all forced them to at least think about new approaches to current challenges. Yet most companies, with a few exceptions, have not yet veered far from the well-worn paths of established business practices.

According to PMC Board member Phyllis Whiteley, an entrepreneur in residence at **Mohr Davidow Ventures**, a venture capital firm in Menlo Park, Calif., there are three “elephants” in the room regarding the business models for personalized medicine. Of different sizes, they all loom large and deter investment. Pharmaceutical companies, rightly or wrongly, must still contend with the assumption that segmenting patient populations inexorably leads to smaller markets and, therefore, decreased revenues and profits. Diagnostic companies believe that, even when successful, they are not financially rewarded in proportion to the value that their tests deliver to patients because they do not share in the increased value of the therapy. And insurance companies argue that they have no incentive to reduce costs by investing in (reimbursing for) preventive care, when those returns are not likely to be seen for years, if at all.

The PMC believes that these elephants, while real, may not be as large as they seem. By providing an answer to the central question “What’s in it for me?” the PMC believes that we can carefully usher the elephants from the room.

In collaboration with the **Deloitte Center for Health Solutions** in Washington, D.C., PMC is seeking to answer the question: “What

is the return on investment for my organization to adopt or invest in targeted therapies?” Based on real examples, the Deloitte Center for Health Solutions is critically examining the business models currently in practice that drive or deter personalized medicine in an effort to identify the incentives that will spur innovation in healthcare.

What’s in it for me?

By analyzing how costs and benefits affect the various stakeholders, we believe that we can better understand the framework that will lead to increased investment. If we understand which stakeholders have the most costs and which can derive the most benefit, we can better negotiate the environment in which key decisions are made. If there are gaps in the business models, as we believe that there are, we will be better positioned to make the case for governmental intervention to increase incentives to invest in more efficacious, safer, and lower-cost healthcare, a clear public benefit. Among those that we are considering in the U.S. are a research and development tax credit for the co-development of therapeutic and molecular diagnostic products, increased public funding for genetic and genomics research, expedited FDA review of personalized medicine products, increased incentives for payer participation in preventive care, automatic reimbursement for FDA-approved diagnostics, and value-based pricing for new diagnostic products.

The Deloitte study, titled “The ROI for Targeted Therapies: A Strategic Perspective. Assessing the Barriers and Incentives for Adopting Personalized Medicine,” will be released at the PMC conference.

In addition to exploring the business models underlying personalized medicine, the conference will also consider policies outlined in the Genomics and Personalized Medicine Act proposed by Senators Barack Obama, Democrat of Illinois and Richard Burr, Republican of North Carolina, in the Senate and by Congressman Patrick Kennedy, Democrat of Rhode Island, in the House of Representatives.

For more information and to register for the conference, *Achieving ROI in Personalized Medicine: Barriers, Incentives, and Pathways to Successful Commercialization*, visit our Web site at www.personalizedmedicinecoalition.org. ■

PMC Announces Two New Board Members



Jeffrey Cossman
The Critical Path Institute
(C-Path)

The PMC is pleased to announce that Jeffrey Cossman, Chief Scientific Officer of **The Critical Path Institute (C-Path)**, and Felix W. Frueh, Vice President of research and development for personalized medicine at **Medco Health Solutions**, have joined PMC's Board of Directors.

"Jeff Cossman is a pioneer in the science of personalized medicine. Felix Frueh has led the effort to incorporate personalized medicine into existing health and science policy inside the government," says Wayne Rosenkrans, PMC's President and Chairman. "Their combined expertise will greatly enhance our efforts to encourage the government to become a more effective supporter of personalized medicine."

Dr. Cossman has been on the cutting edge of research in the field of personalized medicine for the last two decades. He helped found the field of molecular diagnostics, which has grown to become a major tool in personalized medicine, while at the National Cancer

Institute and at **Georgetown University Medical Center**, where he served as Chairman of the Department of Pathology. Prior to joining C-Path, he was Vice President of **Gene Logic Inc.**, where he directed scientific and academic collaborations using microarray gene expression. At the C-Path, he is heading scientific programs that partner with the FDA and industry consortia in an effort to speed the development of new drugs and devices.

"This emerging field of personalized medicine, built on the science of the last 10 or 20 years, carries such great promise," Dr. Cossman says. "Through teamwork across industry, academia, government, and payers, we can fulfill this promise and bring the right treatment to the right patient. The PMC complements the mission of the Critical Path Institute in fostering personalized medicine that grows from improvements in the process of developing medical products."



Felix W. Frueh
Medco Health Solutions

Dr. Frueh spent four years as Associate Director for genomics at the FDA, where he led the core genomics review team at the CDER and chaired the first FDA-wide pharmacogenomics review group. Prior to that work, he founded the firm of Stepoutside Consulting, which provided services to European biotechnology companies interested in establishing a presence in the United States. He has held senior positions at several private laboratories and served on the faculty in the pharmacology and medical departments at Georgetown University.

Someday, genetics will be as common a factor as family history in making treatment decisions, Dr. Frueh said, but only if "technology and its use are promoted appropriately, if stakeholders come and work together, and if ways are found to protect individuals from the misuse of information needed to make such decisions. The PMC is the most important organization at the interface of science, business, and policy, connecting stakeholders, communicating and debating critical policy decisions, and providing a channel to the legislative activities in Washington, D.C.—an activity of growing importance." ■

New PMC Members

23andMe
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Top Officials Outline Personalized Medicine Agenda

Some 150 senior executives, scientists, policymakers, and academic experts gathered last month in Deer Valley, Utah, in an effort to come together around a common vision for personalized healthcare, identify the challenges it faces and strategies for overcoming them, and to develop action plans for the year ahead.

Speakers at the *National Summit on Personalized Health Care*, hosted by Utah Governor Jon M. Huntsman, included HHS Secretary Michael O. Leavitt and Clayton Christensen of Harvard Business School, as well as Senators Bob Bennett and Orrin Hatch, Republicans of Utah. The PMC helped sponsor the event.

Mara Aspinall, Vice Chair of the PMC, summarized the participants' vision, saying, "Personalized healthcare will become the standard approach for all healthcare. This revolution starts with patients and survivors—those coping with disease—then moves to screening and prognostics for those with no evident disease or pre-emergent disease. This revolution means that healthcare is preemptive—looking at disease before clinical symptoms begin. It is predictive—with the ability to anticipate disease and worsening of symptoms. And it is pro-active and participatory. It will use an increasingly wide range of diagnostic tools to inform interventions at the level of *this* patient, *this* disease, and *this* therapy. It will ultimately improve wellness for all."

Five work groups defined strategies for reducing or eliminating barriers to the adoption of personalized medicine:

- In **Business**, the group sought to create commercial incentives, established a task force to develop a new reimbursement framework for diagnostics, and recommended the creation of a new FDA Diagnostic Division for appropriate regulation.
- In **Health Care Delivery**, strategies focused on the selection of exemplar populations with which to generate outcomes to support policy change and to provide quality outcomes at the patient level.
- In **Science**, experts sought to define an "evidence" roadmap and an information technology roadmap.
- In the **People** working group, the emphasis was on establishing a dialogue with patients and developing a language and cultural framework for engaging with patients and consumers—with the ultimate goal of "putting patients first."
- In the "**Utah**" group, it was decided that local leadership should collectively address key goals, connect to the state Health Reform Taskforce, and channel the local resources on delivering the highest quality patient care at the lowest possible cost.

Raju Kucherlapati, Ph.D., Director of the **Harvard Partners Center for Genetics and Genomics** suggested that PMC serve as the central national entity to advance the priorities discussed at the meeting. PMC President and Chairman Wayne Rosenkrans and Executive Director Edward Abrahams reiterated the PMC's commitment to implementing all the strategic priorities for adoption of personalized healthcare. ■



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Genomic and Personalized Medicine Two-Volume Set

Edited by:

Huntington F. Willard, Ph.D. and Geoffrey S. Ginsburg, M.D., Ph.D.

Duke Institute for Genome Sciences & Policy, Duke University, Durham, NC, USA

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David Altshuler MD, PhD, Professor of Genetics and Medicine, Harvard Medical School, Massachusetts General Hospital

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| PMC in the Press

Associated Press reported in October in an article picked up by newspapers across the country that Wisconsin Governor Jim Doyle has unveiled an initiative to make Wisconsin a “world leader in personalized medicine,” but that the plan faces competition from California and other states that have already made similar investments. The group’s first project will be the Wisconsin Genomics Initiative, an effort to learn more about how human DNA relates to diseases. Governor Doyle predicted that the initiative would improve healthcare and reduce medical costs, as well as attracting companies, jobs, and federal grant dollars. PMC Executive Director Edward Abrahams noted that a number of other states have already staked their claims on national leadership in personalized medicine, including California, Massachusetts, North Carolina, and Utah. “The governor is on the right path. I just note he’s not alone,” he said. “Wisconsin has a lot going for it in terms of resource infrastructure, but places like the Bay Area and Cambridge, Mass. have head starts because they’re already centers of biotechnology and innovation.”

Pharmacogenomics Reporter reported last month that Pfizer’s commitment to personalized medicine has been tempered by five external barriers, according to a senior official at the company. Dennis Van Liew, PMC Board member and Senior Director of Pfizer’s Global Research and Development Strategic Management Group, identified five key barriers that must be addressed in order for science to move forward on personalized medicine: an untenable reimbursement infrastructure, divergent Rx/Dx-development timelines, ongoing public suspicion that genetic data may be misused, insufficient education of consumers and professionals, and lack of electronic medical records. “We see those as key barriers, and we have some ideas about how to address those barriers,” Van Liew said. “But we actually think that personalized medicine is reality.”

“*The Pink Sheet*” said in September that AstraZeneca has 10 drug projects that incorporate a diagnostic component under development and is evaluating 20 more, signaling a shift in the company’s approach to integrating personalized medicine. It notes that AstraZeneca developed its focus on integrating personalized medicine during clinical development under the tenure of PMC President and Chairman Wayne Rosenkrans, who was Director of external relations for personalized medicine and evidence-based medicine there before moving to the MIT Center for Biomedical Innovation.

Digital HealthCare & Productivity.com, an online newsletter that covers technology as it relates to improving healthcare productivity, published an interview with PMC Executive Director Edward Abrahams in September that introduced PMC to newsletter readers. He told the interviewer that the future of personalized medicine depends on the ability to aggregate an enormous amount of data. “The ability to do that depends upon the power of computing and health-IT,” he said. “The first thing we need is electronic medical records, and interoperability to gather the data so it’s seamless. This is a lot of work.” PMC is developing a white paper on demonstrating the value of health-IT to improve clinical trials and patient records, among other areas, he said.

The New York Times on August 22 published a letter from PMC Executive Director Edward Abrahams that he wrote in response to an August 17 column by Olivia Jones titled “Testing Genes, Solving Little.” He took issue with the author’s contention that the incorporation of genetics into medicine has been discouragingly slow. “I’d counter that there have been many advances that have allowed physicians to move away from trial-and-error, one-size-fits-all medicine by personalizing treatments,” he wrote. “These include the knowledge that certain oncology drugs work for particular individuals and not others, the capacity to predict the likelihood of breast cancer recurrence and thus avoid costly and painful chemotherapy, and the ability to properly determine the dosage of anticoagulants based on a patient’s metabolism.”

GenomeWeb Daily News said in July that the HHS Secretary’s Committee on Genetics, Health, and Society plans to release a draft report with its recommendations for genetics education by next summer. The PMC also plans to issue recommendations regarding consumer genomics, the webzine reported, and is working with companies including Navigenics, deCode genetics, and 23andMe about strategies they could take that would demonstrate compliance with standards and to assuage concerns about their businesses. PMC may continue to work with the companies to develop “basic guidelines for how these companies should act,” said Amy Miller, PMC’s Public Policy Director. She said the PMC is considering different sets of guidance: one for companies, one for consumers, and one for physicians.

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Edward Abrahams
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