

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

SPRING 2008

Letter from the Executive Director



In a recent speech on healthcare, House Speaker Nancy Pelosi announced that personalized medicine is the “wave of the future.” Informed by her constituents in the Bay area, she understands how advances in science and technology have the power to reshape the discovery, development, and delivery of 21st century medicine.

What she did not say, however, is how the government could or should facilitate the promise of personalized medicine other than to note, as some presidential candidates also have, that overall cost savings can be derived from investment in electronic health records, a necessary but insufficient precondition that will lead to better healthcare decisions in the future.

It is the organizing principle of the Personalized Medicine Coalition that the patients’ interests are served when government sends the correct signals, which encourage investment in personalized medicine across the spectrum from discovery to delivery. Without increased investment, medical progress will be much slower. Suffice it to say, the current system of regulation and reimbursement, born before even the discovery of DNA, is not set up to advance personalized medicine, even when the science supports it. *continued on page 2*

Policy Brief

Market forces alone are unlikely to transform the way that medicines are discovered, developed, and delivered. If personalized medicine is going to change healthcare as members of the PMC hope, it may be necessary for the government to lower advancement barriers and create incentives that support its growth. Based on the assumptions that targeted therapeutics can improve efficacy, reduce adverse events, and reduce the cost of healthcare generally, many in the PMC see a role for government to encourage investment in this new paradigm.

When he introduced the Genomics and Personalized Medicine Act of 2007 (S 976), Senator Barack Obama (D-Ill.) noted that personalized medicine has the potential to improve healthcare and that government intervention might be necessary. Following a public policy meeting with his staff, Senator Obama asked the PMC to articulate ideas that would stimulate investment in personalized medicine. Led by Michael Stocum of **Personalized Medicine Partners** and representing nearly all of the stakeholder groups in the Coalition, the PMC developed a list of legislative incentives for consideration. Congress has a history of authorizing incentives, such as tax credits, to stimulate scientific innovation, which promise to benefit society. Such incentives motivate companies to develop products that market forces alone cannot justify.

continued on page 2

Contributors:

- Edward Abrahams, Executive Director, PMC
- Roxanna Smith, Office Manager, PMC
- Amy M. Miller, Public Policy Director, PMC
- Feinstein Kean Healthcare

President of the Institute of Medicine Addresses Personalized Medicine Coalition

“If personalized medicine is to succeed,” said Harvey V. Fineberg, M.D., Ph.D., President of the Institute of Medicine, “it has to couple ... biologically based [information] with a commitment ... [to] the whole human being.” Delivering the PMC’s Fourth Annual Keynote Address on the State of Personalized Medicine at the National Press Club in Washington, D.C. on March 7th, Dr. Fineberg argued that greater knowledge of genomics and biomarkers alone, as important as it is, cannot address our healthcare problems if they are not tied to “the needs of the human being, the patient, and the family.”

continued on page 3

ALSO IN THIS ISSUE:

PMC Receives Grant from Pfizer	2
The PMC Hosts Bicoastal Receptions	3
PMC Members to Receive <i>Personalized Medicine Journal</i>	4
New PMC Clinical Science Committee Announced	4
PMC Awards Annual Leadership in Personalized Medicine Honor	5
PMC Vice Chair, Mara Aspinall, Appointed to Federal Advisory Committee	5
Genetic Information Nondiscrimination	5
Public Policy Speaker Series	6
New Members	6
PMC in the Press	7
Sponsored Events	8

Letter from the Executive Director *continued from page 1*

To address this conundrum, the PMC's new strategic plan emphasizes three priorities that will govern the Coalition's thinking and activities moving forward as we seek to create a friendlier landscape for the advancement of this new medical paradigm.

- First, knowing that pharmaceutical and biotechnology corporations, diagnostic companies, and insurance companies cannot increase their commitment to personalized medicine in advance of understanding that there will be a return on those investments, the PMC plans to develop and showcase business models that will support innovation and indicate where government policies need to change to assist its growth (see Policy Brief on Page 1);

- Second, the PMC plans to define new pathways that will lead to an evidentiary base of knowledge that can underpin reformed reimbursement policies that will support personalized and preventive medicine products and concepts; and

- Third, the PMC will help build a personalized medicine-informed healthcare workforce by collaborating with providers on the front lines of healthcare.

These are big projects and will supplement our ongoing educational and advocacy efforts that are focused on, among other things, the enactment of the Genetic Information Nondiscrimination Act, the building of a national health information technology

system, and the intelligent regulation of genetic testing that encourages innovation and protects consumer confidence. Realizing these objectives will require intelligence, good will, patience, and funding. But if personalized medicine is indeed the "wave of the future," viable business models will have to be developed; reimbursement must become an ally, not an obstacle, to progress; and physicians and other providers must be willing to adopt new products when they become available. ■

*— Edward Abrahams, Executive Director
Personalized Medicine Coalition*

PMC Receives Grant from Pfizer



The Personalized Medicine Coalition has been awarded a \$75,000 grant from **Pfizer** to support its educational programming.

The funds will be used for two purposes: to enhance the Coalition's public policy meetings and to prepare for a conference later in the year on the business models that will advance personalized medicine. That conference will grow out of a PMC-sponsored study on the subject with the **Deloitte Center for Health Solutions**.

According to Amy Miller, the PMC's Public Policy Director, the grant has given the Coalition an opportunity to engage the many issues that affect our members, including the regulation of genetic testing, privacy, and reimbursement. She said that the PMC offers "government officials from FDA, CMS, and Congress, among others, an opportunity to interact with the multiple constituencies that comprise the PMC in a constructive setting, and the grant will facilitate that effort." Those meetings, she added, "are open to all PMC members, are held on a bi-monthly basis, and are focused on government's role in advancing this new paradigm."

Emily Clements, in Pfizer's Worldwide Public Affairs & Policy division, said when making the grant, that in recognizing and supporting the PMC's mission, Pfizer "intended to signal its commitment to personalized medicine, especially bringing the advances in science, notably in pharmacogenomics, to bear on the lives of patients as rapidly as possible." ■

Policy Brief *continued from page 1*

Designed to cut red tape and subsidize research and development, the PMC suggested the following:

1. A tax credit for research, development, and experimentation for therapeutic and molecular diagnostic combinations;
2. An increase in federal grants for an expansion and acceleration of genetic and genomics research;
3. An expedited FDA approval process for personalized medicine therapeutic and diagnostic products developed together; and
4. An expedited FDA approval process for personalized medicine products developed separately.

More information on these incentives can be found on our website: http://www.personalizedmedicinecoalition.org/objects/pdfs/PMC_Incentives_for_PM_2008_January.pdf

In addition to the list of incentives referenced above, PMC members agree that a coordinating office for personalized medicine at the U.S. Department of Health and Human Services would help the field advance by aligning personalized medicine-related efforts within all of the HHS agencies.

The road from idea conception to legislative reality, as we have seen with the Genetic Information Nondiscrimination Act (GINA), can be long and torturous. But, with Senator Obama running for President and the PMC's active interest in improving the policy landscape for personalized medicine, these ideas could and should be considered. They undoubtedly will be introduced during policy debates surrounding comparative effectiveness as new research offers explanation as to why one course of therapy may work better than another and must, therefore, be incorporated in the science and in the policy. ■

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

I The PMC Hosts Bicoastal Receptions



PMC members and other leaders in personalized medicine gathered at The Broad Institute of MIT and Harvard in January to discuss progress in personalized medicine.

In December 2007 and January 2008, the Personalized Medicine Coalition hosted bicoastal receptions in East Palo Alto, CA, and in Cambridge, MA. These receptions provided opportunities to continue conversations started at similar networking events held in 2005 where key thought leaders in personalized medicine gathered to explore the current field and examine potential obstacles and future advances in personalized medicine.

Held on December 10, 2007 at the Silicon Valley Four Seasons Hotel in East Palo Alto, the West Coast Reception featured remarks by **Brook Byers**, Kleiner Perkins Caufield & Byers; **Susan Desmond-Hellmann**, Genentech, Inc.; and **William Young**,

Monogram Biosciences. The speakers, joined by nearly 100 attendees, reflected on the history of personalized medicine, highlighting advances and the remaining challenges before personalized medicine is widely accepted and regularly used in healthcare.

Susan Desmond-Hellmann discussed how personalized medicine truly impacts and benefits patients through the drug development process. She remarked, "When it [personalized medicine] works, it's magic. It is so much better than doing traditional drug development and trying to do clinical research without the right tools." William Young echoed this commitment to improving patient care, saying that it is ultimately about making a "real difference in patients' lives."

All of the speakers emphasized the importance of collaboration among the many diverse entities in personalized medicine if it is to succeed: diagnostic companies, healthcare professionals, payers, regulatory officials, laboratory companies, investment communities, researchers, patients, and advocates. Brook Byers accurately noted, "This is the chance to revolutionize healthcare, but there is just no way to go it alone."

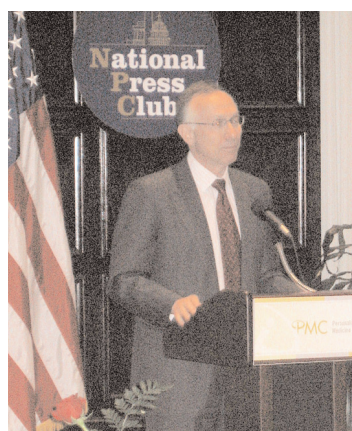
On the East Coast, **Raju Kucherlapati**, Harvard Medical School-Partners HealthCare Center for Genetics and Genomics; **Eric S. Lander**, The Broad Institute of MIT and Harvard; and **Mark Levin**, Third Rock Ventures, gathered with over 100 attendees in the newly renovated lobby of The Broad Institute of MIT and Harvard to explore the past, present, and future of personalized medicine. All of the speakers noted that personalized medicine has made significant progress over the past years. Eric Lander remarked "It is one of the most remarkable periods in genetics that we are living through." The speakers also agreed that personalized medicine has encountered more obstacles than expected, despite the compelling argument for widespread adoption of these new and disruptive technologies.

Mark Levin expressed frustration at the delay. "In order for us to really be proud of what we're doing in this industry," he said, "we need to make better products, and they have to be tied to personalized medicine."

The East Coast speakers, like their West Coast counterparts, also emphasized collaboration as a key to advancing personalized medicine. "The only way that we will be able to advance personalized medicine," stated Raju Kucherlapati, is through "collaborations between the different groups of people—people from the government, industry, and academia, all walks of life—coming together to move personalized medicine forward." ■

President of the Institute of Medicine Addresses Personalized Medicine Coalition

continued from page 1



Dr. Fineberg addresses key leaders in personalized medicine at the National Press Club during PMC's Fourth Annual Keynote Luncheon on March 7, 2008.

Photo courtesy of M. Ulloa

Fineberg likened the American healthcare system to the football prospect who is small but slow. Our system, he said, is the most expensive and far from the best. As measured by life expectancy at birth or by infant mortality, it underperforms, especially when compared to a nation like Singapore, which has surpassed the United States on those two crucial metrics.

Cautioning that linking diagnostics to therapies cannot by itself address the central challenge of the healthcare system today of rising costs and declining productivity, Fineberg noted that it could

nevertheless contribute meaningfully to its improvement. By determining what works, at what dose, and for whom, personalized medicine could, for example, help address the "squeeze" in the pharmaceutical pipeline today. He noted that we have witnessed a steady decline in new chemical entities—in the high teens in the last three successive years and down from more than thirty only six years ago.

He cautioned that proponents of personalized medicine should under-promise and over-deliver. That caveat notwithstanding, Fineberg argued that we need to remove the obstacles to the "wider deployment and use" of personalized medicine. He called on both the public and private sectors to embrace its implications for research and the translation of that research into clinical practice. He argued for rewarding "genuine innovation" in the healthcare system. He proposed a stronger FDA that can stimulate and encourage the co-development of diagnostic and therapeutic products, and he proposed putting in place a reimbursement system that is "value-driven," rather than one that pays for "units of service." And finally, he contended that we must ensure that physicians and other healthcare providers are prepared for the new era we are entering by reforming medical curricula so that the new discoveries of the 21st century are translated into better clinical care.

Concluding that personalized medicine's "promise is real," he said that it "will require action on many levels" before it is realized. ■

PMC Members to Receive *Personalized Medicine* Journal Subscription



The Personalized Medicine Coalition is pleased to announce a new partnership with *Personalized Medicine*. The peer-reviewed journal, published bi-monthly, addresses scientific, commercial, and policy issues in personalized medicine, and it includes news, views, and trends in the field.

Under the terms of the partnership, one nominated individual from each PMC member organization in 2008 will receive a print subscription to the journal. In addition, *Personalized Medicine* will also publish news from the PMC, including its policy positions and proposals designed to advance the field. "The agreement with this leading, international journal," said Edward Abrahams, Executive Director of the PMC, "represents a milestone for the PMC. It will amplify our voice and give us worldwide exposure, enabling the PMC to reach new and wider audiences across constituencies."

Elisa Manzotti, Editorial Director of *Personalized Medicine* noted, "We are delighted to build upon the close working relationship we have enjoyed with the PMC so that the journal reaches the widest possible audience within the healthcare and health policy communities." She noted that *Personalized Medicine* has published many articles by PMC members who are also represented on the journal's editorial board.

Gualberto Ruaño, President and CEO of **Genomas**, a PMC Board member, and one of the senior editors of *Personalized Medicine*, added that he was especially pleased by the new partnership, which, he said, "anticipates not only the synergistic growth of the two organizations but also that of personalized medicine." ■

New PMC Clinical Science Committee Announced



Dr. Eng will head the PMC's restructured Clinical Science Committee.

The PMC is pleased to announce the re-organization of its Clinical Science Committee. Charis Eng, M.D., Ph.D., FACR, Chair and Founding Director of the **Cleveland Clinic Genomic Medicine Institute**, will assume the position of Chair. The first meeting will be on May 1st, from 10:00 a.m. to 12:00 p.m., at the PMC offices in Washington, D.C.

Dr. Eng, who has published over 280 peer-reviewed studies in clinical cancer genetics and cancer genomic medicine, is Professor and Vice Chairman of the Department of Genetics at Case Western

Reserve University and holds joint appointments as Professor of Molecular Medicine at the Cleveland Clinic Lerner College of Medicine and its Taussig Cancer Institute. She is also a practicing genomic medicine physician. The recipient of numerous awards, she is Senior Editor of *Cancer Research* and Associate Editor of both the *Journal of Clinical Endocrinology and Metabolism* and of the *American Journal of Human Genetics*. She serves on the boards of the **American Society of Human Genetics** and the **National Human Genome Research Institute**.

In accepting this role with the PMC, Dr. Eng noted that much work remains to advance personalized medicine. High on the Committee's agenda, she said, would be to:

- Develop new pathways to demonstrate clinical utility for personalized medicine products (in the broadest sense) in addition to the expensive controlled randomized clinical trial;

- Update the PMC's *The Case for Personalized Medicine*, especially its survey of personalized medicine, drugs, treatments, diagnostics, and risk assessment;
- Spotlight the peer-reviewed research of the PMC member institutions; and
- Identify successes and bottlenecks in personalized approaches to medicine by opening dialogs with research institutions and clinical societies.

The Clinical Science Committee, which is open to all PMC members, was created to evaluate the emerging applications of science and technology in personalized medicine. It serves as an advisory resource for the PMC, and it helps guide policies and statements by the organization in its effort to advance personalized medicine in the public sphere. The Committee also oversees material published on the PMC's websites and in its other publications. It will be staffed by Jerry Goldsmith, who is retiring from his position as Vice President for Marketing Programs at **AACC (American Association for Clinical Chemistry)**.

Wayne Rosenkrans, Jr., Ph.D., President and Chairman of the PMC, and Scientific and Medical Strategy Director for External Scientific Affairs at **AstraZeneca Pharmaceuticals**, said that he "looked forward to the leadership that Dr. Eng would provide to help unify and direct critical work across the United States and the world in personalized medicine," and he urged each PMC member institution to nominate someone to participate on the Committee before the first meeting on May 1st.

Please send those nominations to rsmith@personalizedmedicinecoalition.org ■

PMC Awards Annual Leadership in Personalized Medicine Honor at Personalized Medicine Conference



Mara G. Aspinall presents the 2007 Leadership in Personalized Medicine Award to Dr. Snyderman.

Photo courtesy of The Harvard Medical School—Partners HealthCare Center for Genetics and Genomics

The Personalized Medicine Coalition presented the 2007 Leadership in Personalized Medicine Award to Ralph Snyderman, M.D., Chancellor Emeritus at **Duke University**, and Founder and Chairman of **Proventys**, for his efforts in advancing predictive and targeted therapies on a national scale, at an awards ceremony during the November **Harvard Medical School – Partners HealthCare Center for Genetics and Genomics (HPCGG)** and Harvard Business School conference, *Personalized Medicine: A Call for Action*, in Boston, MA.

This award, given annually by the PMC, recognizes a visionary individual whose actions in science, business, or policy have advanced the

frontier of personalized medicine. Dr. Snyderman's early work as an immunologist at Duke University Medical Center in 1972 and as a Vice President (later Senior Vice President) at Genentech, as well as his transformative activities while serving as Chancellor of Health Affairs at Duke from 1989 to 2004, demonstrate a long-term commitment to studying the important role that emerging technologies play in the advancement of personalized medicine.

Dr. Snyderman's work while serving as the Chancellor of Health Affairs at Duke demonstrates his leadership in the field of personalized, targeted therapy. Dr. Snyderman developed a comprehensive healthcare approach based on the concept of "Prospective Health Care." The foundation of this healthcare approach is strategic, personalized, and predictive health planning, rather than reactive treatment. As a successful and integral part of the Duke Health System for six years, "Duke Prospective Health" uses technology to provide individualized and integrated healthcare for patients.

The award was introduced by Edward Abrahams, Executive Director of the PMC, who commended Dr. Snyderman's "innovative and influential work" in personalized medicine. Mara G. Aspinall, of **Genzyme Genetics**, Vice Chair of the PMC, and Chair of the committee that selected Dr. Snyderman, presented the award to him and also highlighted his many contributions, stating that "Dr. Snyderman has helped advance the frontier of personalized medicine across a broad front, including clinical care, business, and as an outspoken supporter of the new paradigm." ■

PMC Vice Chair, Mara Aspinall, Appointed to Federal Advisory Committee

Mara G. Aspinall, of **Genzyme Genetics**, and Vice Chair of the PMC, has been appointed to the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS). A 15-member panel, SACGHS advises the Secretary of Health and Human Services on policy issues raised by the development and use of genetic technologies and their integration into clinical and public health practices. Genzyme, one of the world's foremost biotechnology companies, is an active member of the PMC, and Aspinall will use her extensive experience as former President of both Genzyme Pharmaceuticals and Genzyme Genetics to further address obstacles facing the widespread adoption of personalized medicine. Her strong background in both diagnostics and therapeutics gives her a unique perspective on personalized medicine, especially in the development and marketing of combination products.

Aspinall commented that as Vice Chair of the PMC and now also a member of the Secretary's Advisory Committee, she is "well-positioned to advance some of the arguments that we [Aspinall and Richard G. Hamermesh] wrote about in 'Realizing the Promise of Personalized Medicine,'" an article published in the *Harvard Business Review* in October 2007. ■

Genetic Information Nondiscrimination

According to a recent *New York Times* article, fears regarding discrimination in employment and insurance stifle the use of genetic tests. The PMC has worked hard to help pass the Genetic Information Nondiscrimination Act (HR 493/S 358; GINA), a bill that would bar employers and insurers from using genetic information to discriminate against employees in hiring and benefit decisions. GINA has been debated by Congress and, although passed by the House, awaits Senate action. On March 5, 2008, the U.S. House of Representatives passed GINA for the second time this session, as part of the Paul Wellstone Mental Health and Addiction Equity Act. The House did so to force Senate action on GINA, though the Mental Health Parity bill has its own controversies.

GINA is stalled in the Senate over concerns that it would encourage frivolous lawsuits and that its relationship to other relevant laws is not clear. In a recent Statement of Administration Policy, the White House said that it looks forward to working with Congress to pass the Mental Health Parity bill and GINA this year, though significant differences remain.

The PMC is pleased that two of our largest members, **IBM** and **Eli Lilly Corporation**, have added genetic nondiscrimination to their employment policies. In mid-2005, IBM became the first major corporation to do so. As IBM Chair and CEO Samuel J. Palmisano stated in a letter to employees when the policy was instituted, "The opportunity the world has to improve life in the century ahead through genomics-driven, personalized medicine and preventative care will only be realized fully if it also takes into account the protection of genetic privacy."

When announcing its policy in mid-2007, Eli Lilly Vice President of Medical Projects Eiry Roberts said that genetic information "will provide value to the patient, physician, and payer" by introducing higher quality, more efficient healthcare, but that fear of genetic discrimination "could have grave consequences on future patient care and continued scientific discoveries."

To show support for a continued focus on preventing genetic discrimination, PMC members are urged to issue similar policies in their organizations. ■

Public Policy Speaker Series: Dr. Kathleen Behrens, PCAST

Continuing the tradition of engaging policy makers in active dialog, the Personalized Medicine Coalition invited M. Kathleen Behrens, Ph.D., Chair of the President's Council of Advisors on Science and Technology (PCAST) Personalized Medicine Subcommittee, to address members of the PMC at the January 9, 2008 meeting of the Public Policy Committee. Dr. Behrens outlined and discussed the eight policy areas under evaluation and welcomed comments on them. The eight areas are as follows:

1. Regulation of therapies and diagnostics by FDA and CMS;
2. Reimbursement of therapies and diagnostics by CMS and private insurance companies;
3. Genomic diagnostics, intellectual property, and related emerging patent issues;
4. Patient privacy;
5. Information technology and issues of electronic patient records and associated data/databases;
6. Economics of personalized medicine;
7. Personalized medicine technology and tools; and
8. Patient, physician, and public education.

PMC members took advantage of the opportunity to voice their opinions on the regulation of genetic tests by stressing that in the current environment, innovative companies too frequently cannot assume a return on their investment given the uncertain regulatory system and the lack of coverage by private and public insurance plans. In response to a question about what would help, PMC members urged PCAST to incorporate incentives for personalized medicine in the report (see Policy Brief on Page 1). Members also commended Secretary of Health and Human Services Michael O. Leavitt's Personalized Health Care Initiative and expressed their hope that an Office of Personalized Health Care would be established in the Immediate Office of the Secretary and that it would survive the administration change.

The Personalized Medicine Report to the President is expected to be released this summer. With an agenda parallel to much of the PMC's work, it could guide the next administration as it tackles difficult healthcare issues.

For more information on PCAST, please visit:
<http://www.ostp.gov/cs/pcast> ■

Public Policy Speaker Series: Dr. Steven Gutman, FDA

Steven Gutman, M.D., Director of the Food and Drug Administration's Office of In Vitro Diagnostics (OIVD), addressed the PMC at the March 11, 2008 meeting of the Public Policy Committee. In his address, Dr. Gutman reviewed the FDA's role in the regulation of genetic tests and of co-developed products.

Because of the FDA clearance process, he was unwilling to give an estimated publication date for the much-anticipated guidance on the regulation of co-developed products. He also said that federal regulation of genetic tests is a focus of two forthcoming reports: one from the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) and another from the President's Council of Advisors on Science and Technology (PCAST). Both reports, he suspects, may influence the thinking and deliberations at FDA over the coming year.

FDA has recently released a number of guidance documents related to personalized medicine, including their most recent guidance on *in vitro* diagnostic multivariate index assays (IVDMIA's). During a presentation at the 3rd Annual Burrill Personalized Medicine Conference, held in

November 2007 in San Francisco, Dr. Gutman responded to the audience's concern about the guidance by stating that alternative models of regulation submitted to the docket would receive his office's attention. A number of groups have submitted alternative models, and Dr. Gutman gave a brief overview of each.

He emphasized that FDA regulation of genetic tests focuses on the risk of the test and the indications described in the label, and he invited industry to engage FDA "early and often" with questions about products, processes, or guidance. His office, he assured the audience, provides "free" consulting services, and he hopes that industry will take advantage of that service. The PMC offers FDA a similar option. If future guidance is under consideration, FDA has an open invitation to use the PMC as a venue to consult with all relevant stakeholder groups.

For more information on all FDA guidance documents, both draft and final, visit:
<http://www.fda.gov/ohrms/DOCKETS/>

For more information on OIVD, visit:
<http://www.fda.gov/cdrh/oivd/> ■

New Members

PMC Welcomes the Following New Members since October 2007:

5AM Ventures

AMGEN, Inc.

BioMarker Strategies

Children's Hospital Oakland Research Institute

Corbett Accel Healthcare Group

Coriell Institute for Medical Research

Endo Pharmaceuticals

Gene Express, Inc.

Gene Network Sciences

Georgetown University School of Nursing & Health Studies

Hadassah The Women's Zionist Organization of America

Health Futures, LLC

HP Health and Life Sciences

Humana, Inc.

Hypertrophic Cardiomyopathy Association-HCMA

Institute for Genomic Medicine, UMDNJ-New Jersey Medical School

Interleukin Genetics, Inc.

Lineagen, Inc.

Navigenics, Inc.

Progenika

Proventys

REDPATH Integrated Pathology, Inc.

Rosetta Genomics

Siemens Medical Solutions

Third Rock Ventures, LLC

Ventana Medical Systems

PMC in the Press

The Wall Street Journal on March 24th reported on the links between genes and diseases as a major influence on drug development in the article, "Genetics May Bring New Life to Failed Drugs." The writer explains how the broader shift toward personalized medicine, or tailored therapies, dovetails with pharmaceutical makers' recognition of how hard it is to maintain a business model that relies on producing a few drugs that bring in billions of dollars a year. Wayne Rosenkrans, Jr., President and Chairman of the Personalized Medicine Coalition, notes the rising importance of personalized medicine. "The old sort of pharmaceutical model is under pressure right now," he stated. "Personalized healthcare is one of those potential solutions."

Standard & Poor's reported in March on the impact new developments in personalized medicine will have on the pharmaceutical industry. The writer notes that these new kinds of drugs that are tailored more specifically to subsets of patients, often with the help of genetic tests, will require drug companies to rethink the "one-size-fits-all" business model upon which their research, marketing, and sales organizations are based. The writer continues, stating that personalized medicine looks like pharma's best option, given the industry's current and well-publicized problems with R&D productivity and cost overruns. Edward Abrahams, Executive Director of the Personalized Medicine Coalition, notes that despite the FDA's general support, the field is moving slowly. It needs a clearer regulatory pathway, better business models, and payer support, he said.

FDA Week reported in February on the reactions of key players in the molecular diagnostics field to the FDA's final guidance issued January 30th in the article, "Device Firms Dislike FDA's IVD Guide, Others Give It Lukewarm Praise." The guidance clarifies what criteria *in vitro* diagnostic device manufacturers must meet for exemption from requirements under the Clinical Laboratory Improvement Amendments (CLIA). While the PMC does believe that the guidance gives more clarity, it also calls on FDA to publish a side-by-side analysis of FDA's device regulation for manufacturers of IVD kits and CMS's CLIA regulations for laboratories developing diagnostic test services to compare overlapping authorities.

The Arizona Daily Star reported in January on Roche Holding AG's purchase of **Ventana Medical Systems** in Tucson, Arizona noting that the purchase will validate the region's future as a biotech center. In the article, "Swiss Drug Giant Buys Ventana Medical: \$3.4B Deal Keeps Group in OV, Ratifies Area As Biotech Hub," experts say that what matters in the deal is the growth of so-called personalized medicine, in which patients receive individualized drug therapies. Edward Abrahams, Executive Director of the Personalized Medicine Coalition, remarks on the purchase, "It's a very aggressive move on the part of Roche to pave the way for what we believe is the future of medicine."

Pharmacogenomics Reporter wrote in December about Secretary of Health and Human Services Michael O. Leavitt and his commitment to personalized medicine in the article, "HHS Chief Leavitt May Leave in '09; Vows to Keep Personalized Medicine Center Stage." The writer emphasizes the important contributions that Leavitt has made in advancing personalized medicine. Edward Abrahams, Executive Director of the Personalized Medicine Coalition, also believes that the advances will continue, despite Leavitt's term ending in 2009, saying that "This is a tall agenda that's not going to be done in the first hundred days or even next year." He continues, "But these are important initiatives. No one thought this was going to be easy or depend on the efforts of an administration or single individual."

For links to these and other PMC-related articles, visit the Communications section of our website at:

<http://www.personalizedmedicinecoalition.org/communications/overview.php>

Sign up

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

www.PersonalizedMedicineCoalition.org

Upcoming Events:

5th Annual World Health Care Congress

April 21 – 23, 2008

Washington, D.C.

This event, sponsored by World Congress, brings together chief and senior executives from all sectors of healthcare. The 2008 conference will convene over 2,000 CEOs, senior executives, and government officials from the nation's largest employers, hospitals, health systems, health plans, pharmaceutical and biotech companies, and leading government agencies. **Joanne Armstrong**, PMC Board Member; **Mara Aspinall**, Vice Chair of the PMC; and **Wayne Rosenkrans, Jr.**, President and Chairman of the PMC, will speak in a panel on personalized medicine, moderated by **Edward Abrahams**, Executive Director of the PMC. *PMC members receive a \$300 discount (use code: TBJ486).*

For more information, visit the conference website:

<http://www.worldcongress.com/events/HR08000/?confCode=HR08000>

Personalized Medicine 2008: Optimizing efficiency of your R&D strategy through effective investment in the tailored and personalized medicine arena

May 22 – 23, 2008

London, England

This event, produced by Pharma IQ, is designed to help attendees increase their understanding of regulatory requirements, discuss developments in personalized medicine that can impact businesses, and to understand current and future challenges. **Amy Miller**, PMC Public Policy Director, will be giving an address entitled, "Personalized Medicine: The Changing Landscape of Healthcare."

For more information, visit the conference website at

<http://www.iqpc.com/ShowEvent.aspx?id=70460>, call 44(0)20 7368 9300, or email enquire@iqpc.co.uk

Personalized Medicine Series: The Genomic Revolution in Cardiac Care

June 12, 2008

Washington, D.C.

The George Washington University's Richard B. and Lynne V. Cheney Cardiovascular Institute & McCormick Genomics Center are hosting a series designed to introduce and update practicing internists and cardiologists, as well as health policy analysts, about the current state of knowledge in cardiovascular genomics. Genomas CEO and PMC Board Member, **Gualberto Ruaño**, will be developing the luncheon program that follows the Grand Rounds lecture by Kári Stefánsson, M.D., CEO and co-founder of deCODE genetics. This event is open to PMC members.

For more information, visit the Institute's website:

www.cheneycardioinstitute.org

Molecular Diagnostics

June 24 – 25, 2008

Brussels, Belgium

This new event, produced by Informa Life Sciences, provides an integral forum for leaders in molecular diagnostics, *in vitro* diagnostics, biotech, pharma, and laboratories to share ideas and network, and to answer key questions such as: Where is this industry headed, and which key segments will drive molecular diagnostics growth?

Edward Abrahams, Executive Director of the PMC, will speak at the event. *PMC members receive a 15% discount (Quote CQ7053PMC).*

For more information, visit the conference website:

<http://www.iir-events.com/IIR-Conflpage.aspx?id=11778>

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

http://www.personalizedmedicinecoalition.org/newsevents/event_calendar.php