

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.

Conference Will Examine Role Personalized Medicine Can Play in Comparative Effectiveness Research

RECOGNIZING THE CRITICAL role that evidence-based personalized medicine approaches can play in improving healthcare, the Personalized Medicine Coalition (PMC) and the **National Pharmaceutical Council** will host a conference that is directly related to the government debate over healthcare reform in Arlington, Va. on October 28.

Top policymakers, academics, and business officials will discuss the intersection of comparative effectiveness research (CER) and personalized medicine at the conference, “Comparative Effectiveness Research and



Senator Max Baucus

Personalized Medicine: Policy, Science, and Business.”

Policymakers increasingly see CER as a means to improve quality and consistency and maximize value in the healthcare system. They are coming to see how medicine based on measurable evidence can improve healthcare.

Among those invited to speak at the conference are Senate Finance Committee chairman Max Baucus,

D-Mont., who has been a leader on the issue and has co-authored legislation to help incorporate personalized-medicine principles into CER. Also invited are Kathleen

Sebelius, Secretary of the Department of Health and Human Services, and Elias Zerhouni, M.D., senior fellow at the Bill & Melinda Gates Foundation.

CER has traditionally used broad population averages as a means to compare and evaluate different treatments and health interventions. But as molecular science, health information technology, and new research methods mature, it is crucial that CER take full advantage of our emerging knowledge of the way different patients respond differently to treatment, PMC’s top official said.

“It is critical to incorporate our emerging understanding of molecular medicine into comparisons of the effectiveness of different

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From the Executive Director

‘Precision Medicine’ Will Transform Healthcare, New Book Argues

BASED ON THE TWIN assumptions that people are different and therefore should be treated differently and that knowing what works and why is better than guessing, the Personalized Medicine Coalition contends that decision-makers should invest in the new paradigm we call personalized medicine by putting in place policies that will lead to its more rapid development and adoption. While it is extraordinarily difficult to turn a battleship such as the healthcare system even a



few degrees, PMC has been successful in making its case and in turning that battleship in subtle but perceptible ways because our argument is so compelling.

Ours is an evolutionary vision, one that is subscribed to by multiple stakeholders ranging from venture capitalists to large pharmaceutical companies, and from payers to patient advocacy groups. As we have written in *The Case for Personalized Medicine*, we foresee a day when “personalized medicine” will be known,

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Policy Brief

PMC Brings Personalized Medicine Into Health Reform Debate

HEALTHCARE REFORM IS IN FULL SWING this summer. President Obama recently reiterated his desire to have a health reform bill on his desk before the end of October. House and Senate leaders say they intend to meet that deadline, but observers speculate it may slip.

Overall, the healthcare reform debate has focused on access, cost, and how to pay for expanded coverage. One area of reform in which personalized medicine has figured prominently is comparative effectiveness research (CER). PMC has helped integrate principles of personalized medicine into a Senate bill that could be incorporated into healthcare reform legislation (see Policy Update). Unfortunately, the House version of healthcare reform does not recognize personalized medicine's role in CER at all.

To date, the Administration has delivered four reports to Congress on comparative effectiveness research mandated by the *American Recovery and Reinvestment Act*. Two tip their hats to personalized medicine. Using these reports as guides, Secretary of Health and Human Services Kathleen Sebelius must now outline the federal government's plan for such research and deliver it to Congress.

Healthcare reform legislation and reports on comparative effectiveness are but the first steps down a long road. PMC will continue to urge Congress and the executive branch to develop policies that support the principles of personalized medicine in its work on comparative effectiveness and on other matters including regulation, reimbursement, and



encouraging innovation in personalized medicine.

If Congress fails to enact CER provisions that are informed by molecular medicine, the Genomics and Personalized Medicine Act will provide a second chance for PMC to make an impact. We expect that Senator Robert Menendez, D-N.J., Senator Richard Burr, R-N.C. and Representative Patrick Kennedy, D-R.I. will introduce updated versions of the Genomics and Personalized Medicine Act. We can use the legislation as a vehicle to advance our agenda and make improvements as needed to whatever comparative effectiveness legislation becomes law.

We support a Genomics and Personalized Medicine Act that would:

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Policy Updates

• Senate Bill Incorporates PMC Changes

A key Senate staff member thanked members of PMC's Public Policy Committee for their work on a comparative-effectiveness bill at the committee's meeting in June. Sarah Kuehl, Budget Analyst for the United States Committee on the Budget, Majority Staff, said the bill adopted many of PMC's suggestions for incorporating personalized medicine principles into the Patient-Centered Outcomes Research Act of 2009 (S.1213) to compare the effectiveness of different treatments.

Changes PMC Negotiated in Senate CER Bill:

- expand the research agenda to include primary research on molecularly informed trials
- define potential differences to include genetic and molecular sub-typing
- add experts in molecular diagnostics to the methods panel

The bill's authors, Senator Max Baucus, D-Mont., and Senator Kent Conrad, D-N.D., aim to incorporate the measure into healthcare reform legislation. Kuehl asked PMC members to tell their lawmakers they back the bill, to help shore up support. PMC has written a letter to Senator Baucus and Senator Conrad

that supports the bill as long as the language continues to reflect the principles of personalized medicine. A copy of PMC's letter can be found at <http://www.personalizedmedicinecoalition.org/objects/pdfs/BaucusConrad-ltr-6-24-09.pdf>.



Francis S. Collins, M.D., Ph.D.

• Obama's Newest Health Pick

Francis S. Collins, M.D., Ph.D., a physician-geneticist noted for his landmark discoveries of disease genes and as the leader of the U.S. government effort to map the human genome and to incorporate genetics into medicine, has been confirmed as director of the National Institutes of Health. Dr. Collins was the keynote speaker at PMC's first annual State of Personalized Medicine luncheon in 2005 and is a strong proponent of personalized medicine. A copy of PMC's press release on the nomination can be viewed at <http://www.personalizedmedicinecoalition.org/communications/pr.php?id=8>.

• HIT White Paper to Be Released Soon

Work on a white paper about the role of health information technology in facilitating personalized healthcare is almost complete. A taskforce including **IBM Healthcare and Life Sciences, McKesson** and others has been working on the

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- Codify into law the Personalized Healthcare Initiative of the Secretary of Health and Human Services;
- Streamline the review process for drug-diagnostic companion products;
- Accelerate personalized medicine through tax credits for the research and development of companion products; and
- Offer a patent extension for drug-diagnostic companion products.

At FDA's suggestion, PMC has formed a work group to develop recommendations for updating the April 2005 concept paper on co-developed drug and diagnostic product regulation. Because PMC represents all of the stakeholder groups on this issue, including pharmaceutical, diagnostic and laboratory-services industries, as well as practitioners and pharmacy-benefit

managers, we are well positioned to help shape this policy. We expect to send our work to the agency in the fall.

Personalized medicine has entered the national discourse this year, due in part to concerns that healthcare reform could limit access to innovative therapies, and in part to the appointment of an advocate for personalized medicine, Francis S. Collins, M.D., Ph.D., to be the next director of the National Institutes of Health. The elevation of personalized medicine into the mainstream is a major step for our coalition. On behalf of our increasingly

large and broad membership, we are prepared to take advantage of the many emerging opportunities it presents.

Amy Miller
Public Policy Director



U.S. HOUSE EDUCATION AND LABOR COMMITTEE

Education and Labor Committee members listen to testimony on the Affordable Health Choices Act, part of the health reform proposal being debated in the U.S. House of Representatives.

white paper, which will help to clarify the connections between personalized medicine and HIT and will show how these components relate to health reform. Because the *American Recovery and Reinvestment Act* includes extensive HIT provisions, the paper will also address how the HIT funding can enable, rather than impede, the shift towards a high-performance personalized healthcare system. The paper is slated for release in early October.

• **Companion Diagnostics Recommendations Near Completion**

Last year, Lawrence Lesko, Ph.D., F.C.P., Director of the Office of Clinical Pharmacology of the FDA urged PMC members 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 is completing recommendations to revise the concept paper. The workgroup is also compiling a list of possible white papers for the FDA to publish on the subject. The group expects to send its suggestions to PMC's policy and science committees in September.

• **PMC Submits Comments to Federal Agencies**

In statements to the Federal Coordinating Council on Comparative Effectiveness Research (the Council), the Institute of Medicine (IOM), and the Agency for Healthcare Research Quality (AHRQ), PMC recommended ways that personalized medicine concepts and technologies could be incorporated into comparative effectiveness research. PMC urged IOM and the Council to consider the full range of research questions in CER, from the types of medical intervention administered to delivery of care, and suggested that

each organization designate a permanent standing committee on personalized healthcare. The Council report is public and can be viewed at <http://hhs.gov/recovery/programs/cer/cerannualrpt.pdf>. The IOM publication can be read and purchased at <http://www.iom.edu/CMS/3809/63608/71025.aspx>.

• **PMC Works to Improve GPMA**

PMC, which is working with Senators Richard Burr, R-N.C., Robert Menendez, D-N.J., and Representative Patrick Kennedy, D-R.I., on the Genomics and Personalized Medicine Act, has been helping to draft a new version of the bill, and is seeking a House Republican to co-sponsor the measure.

• **PMC Declines to Support Kyl Bill**

In June, Senator Jon Kyl, R-Ariz., introduced the Preserving Access to Targeted, Individualized, and Effective New Treatments and Services (PATIENTS) Act of 2009 (S. 1259). The bill would ensure that CER would account for advances in genomics and personalized medicine while taking into account unique sub-populations, patient preferences, and differing treatment responses. But it also would have prevented any comparative effectiveness research funded by the *American Reinvestment and Recovery Act* from being used in federal insurance coverage decisions. For that reason, PMC declined Senator Kyl's request to support the bill. The coalition supports the use of personalized medicine principles in CER, but it opposes any effort to limit the application of scientifically sound research in health coverage decisions.

Charissa Wong

Comparative Effectiveness Research and Personalized Medicine: Policy, Science, and Business

In the past year, comparative effectiveness research (CER) has become one of the most intensely debated areas of the U.S. biomedical enterprise. The Obama administration's emphasis on CER as a means to grapple with the huge challenge of healthcare, followed by increased funding of \$1.1 billion for CER included in the American Recovery and Reinvestment Act, have catalyzed a growing debate.

To examine the role that CER will play in the future of healthcare and to explore the intersection of CER with personalized medicine, the National Pharmaceutical Council and the Personalized Medicine Coalition will co-host **Comparative Effectiveness Research and Personalized Medicine: Policy, Science, and Business**, a conference that will bring together leaders from government, industry, and academe. The conference will be directly relevant to forthcoming policy decisions on patient choice and cost containment, as well as being perfectly timed for discussion of CER implementation.

At this conference, speakers and attendees will:

- Provide an update and analysis of government CER activities and define key elements of policy that can facilitate or impede CER in stratified populations.
- Define the scientific and operational imperatives associated with personalized medicine approaches to CER and how policy decisions can affect them.
- Examine the strategic implications of CER policies and programs and how they will affect business models and innovation.

In addition to keynote presentations, the conference will include interactive panel presentations on such topics as:

- *Personalized Comparative Effectiveness Research: Policy Considerations*
- *Opportunities for a Personalized Medicine Approach to Comparative Effectiveness Research*
- *Business Implications of Comparative Effectiveness Research with Stratified Populations*

Final program details and registration information are available at: www.personalizedmedicinecoalition.org.

Please contact amee.jack@fkhealth.com with any questions.

INVITED SPEAKERS

- Senator Max Baucus, D-Montana
- Dr. Stephen Cha, Healthcare Advisor to Representative Henry A. Waxman, D-California
- Dr. Carolyn Clancy, Agency for Healthcare Research and Quality (confirmed)
- Dr. Francis Collins, National Institutes of Health
- Dr. Denis Cortese, Mayo Clinic
- Dr. Jeffrey Cossman, The Critical Path Institute (confirmed)
- Dr. Robert Epstein, Medco Health Solutions (confirmed)
- Adolph Falcón, National Alliance for Hispanic Health (confirmed)
- Dr. Louis Garrison, University of Washington
- Dr. Cliff Goodman, The Lewin Group (confirmed)
- Senator Orrin Hatch, R-Utah
- David King, Laboratory Corporation of America
- Dr. Newell McElwee, Merck & Co. (confirmed)
- Dr. Lewis Sandy, UnitedHealth Group
- Dr. Randy Scott, Genomic Health
- Greg Simon, Pfizer (confirmed)
- Neera Tanden, HHS
- Cole Werble, The RPM Report (confirmed)
- Dr. Janet Woodcock, FDA (confirmed)
- Dr. Elias Zerhouni, The Bill & Melinda Gates Foundation; Johns Hopkins Medicine

PMC Highlights Warfarin Testing Advances

IN A LETTER POSTED BY THE *ANNALS OF Internal Medicine* on its website, the heads of the Clinical Science Committee of the Personalized Medicine Coalition comment on a recent study that genetic testing before initial warfarin dosing is not cost-effective.

Clinical Science Committee co-chairs Jeffrey Cossman, M.D. and Charis Eng, M.D., Ph.D., noted in their letter to the journal that recent developments make genetic testing for warfarin sensitivity both cheaper and more effective than the study suggests. Dr. Cossman is Chief Scientific Officer of the Critical Path Institute and a PMC board member. Dr. Eng is Chair of the Genomic Medicine Institute at the Cleveland Clinic.

The study was outlined in a January 20 article titled “Cost-Effectiveness of Using Pharmacogenetic Information in Warfarin Dosing for Patients With Nonvalvular Atrial Fibrillation.”

A meta-analysis of three randomized trials conducted between 2005 and 2008, the study analyzed the extent to which pharmacogenetic-guided dosing decreases the risk of major bleeds when combined with standard warfarin induction. In a typical case, “genotype-guided dosing resulted in better outcomes, but at a relatively high cost,” the study found, based on the assumption that the genetic test would cost \$400.

Warfarin tests may be cost-effective if they are given to patients who are at high risk of hemorrhage in certain circumstances, the study said.

PMC’s letter pointed out that since the trials underlying the study were conducted, costs of the tests for hospitals or clinics have fallen, and are now much lower than the \$400 the authors estimated, as low as \$50 to \$75 per test, or about \$150 to \$225 if positive



and negative controls are run with each test.

“Given the advances in technology, we suspect the price point will drop further and therefore, make this test not only cost-effective but also beneficial (‘clinically worthy’) to the patient,” they wrote.

What’s more, warfarin tests can now be turned around in as little as 45 minutes from patient to calculated dose, with most in the range of two to six hours and results obtainable in no more than 24 hours, the science committee co-chairs said. (The University of Cincinnati researchers had assumed a result would take about three days.)

Better measures might include the number of times a patient must get a new prescription filled or visit a clinic for an International Normalized Ratio (INR) measurement, which measures how long it takes a patient’s blood to clot compared to the average value in healthy people; the change between initial and final warfarin dose; or how long it takes a patient to achieve a stable INR.

The authors also commented on the common practice of gauging warfarin effectiveness by whether patients begin to bleed. Bleeding is a rare event, they note, especially since caregivers in common study settings like state-of-the-art anti-coagulation clinics or academic medical centers of excellence likely would adjust a patient’s warfarin dose before it could occur. Better measures might include the number of times a patient must get a new prescription filled or visit a clinic for an INR measurement, the change between initial and final warfarin dose, or how long it takes to reach stable INR. A copy of the letter is available on PMC’s website at http://www.personalizedmedicinecoalition.org/sciencepolicy/science_overview.php.

Elizabeth Schwinn

October Conference to Examine Comparative Effectiveness

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therapies,” said Wayne Rosenkrans, Ph.D., Distinguished Fellow at the MIT Center for Biomedical Innovation, and PMC’s president and chairman. “We need to help policymakers understand why and how personalized medicine should be integrated into any analysis of the effectiveness of medical care. When it comes to medicine, one size does not fit all.”

Dan Leonard, President of the National Pharmaceutical Council, concurred. “The ability to target medicines more specifically to patient groups is a significant change in the landscape. Targeted medicine can positively affect innovation and lead to increased benefits for patients. That’s why it’s important to define the intersection of CER and personalized medicine in a way that encourages innovation and benefits

patients,” he said.

Some \$1.1 billion has already been set aside for comparative effectiveness research in the *American Recovery and Reinvestment Act*, helping spur the growing debate on the topic. Policy-makers are still negotiating how the research will be conducted, how much will be invested in it, what entities will oversee it, and how results will be used to drive clinical and reimbursement decisions.

In addition to funding questions,

Policy makers are still negotiating how the research will be conducted, how much will be invested in it, what entities will oversee it, and how results will be used to drive clinical and reimbursement decisions.

topics at the conference will include an analysis of government CER activities; examination of scientific and operational imperatives associated with personalized medicine approaches to CER; and a review of the strategic implications of CER policies and programs in regard to business models and innovation.

The conference will be held at The Ritz-Carlton, Pentagon City, 1250 South Hayes Street, Arlington, Va.

To register, please visit www.personalizedmedicinecoalition.org.

Susan Kahan

Controversy Flares Over Gene Patents

By Andrea Tiglio, Matthew Hinsch and Richard Meyer, Townsend and Townsend and Crew

THE ABILITY OF BIOTECHNOLOGY companies to patent genes is under challenge in two court cases that could have far-reaching implications for genetic medicine.

The American Civil Liberties Union (ACLU) and a number of plaintiffs have filed suit against gene patents held by Myriad Genetics (*Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.*). If successful, the Myriad suit would overturn the long-held view that isolated genes can be patented.

Genes have been considered patentable subject matter since the 1980 landmark Supreme Court case of *Diamond v. Chakrabarty*, which noted that Congress intended for patentable subject matter to include “anything under the sun that is made by man.” Since then, the United States Patent

and Trademark Office (USPTO) has regularly issued gene patents with the requirement that the gene sequences be “isolated” (e.g., isolated apart from their naturally occurring context as part of DNA) and “useful.” There is no established definition for gene patents, but such patents have included claims on either the isolated gene itself or a method of using the isolated gene (e.g., a diagnostic gene test).

The ACLU seeks to invalidate seven gene patents held by Myriad on two isolated human genes, BRCA1 and BRCA2, and their use in diagnostic gene tests to diagnose a predisposition for breast and ovarian cancer. Myriad vigilantly defends its patents and has sent cease-and-desist letters to universities whose researchers were conducting BRCA-related research, and to laboratories providing BRCA-related clinical services.

The ACLU argues that Myriad charges high licensing fees and does not license its patents broadly, unlike some corporate gene patent holders that widely grant low-cost licenses to researchers. According to

the ACLU’s complaint, licensing practices such as these may affect a patient’s ability to obtain a second opinion from someone other than the patent holder or prevent laboratories from externally validating the genetic test offered by the patent holder.

Even as both sides debate the isolated gene patents at issue in the Myriad case, new filings for such patents are increasingly rare. The Human Genome Project, which was completed in 2003, sequenced and published nearly all 25,000 human genes. These gene sequences are no longer considered novel for the purposes of patentability because they were placed in the public domain. Consequently, most new patents referencing a human gene must specify a new use, such as a diagnostic test that relies on the analysis of that gene.

A separate case on business method patents may have even bigger implications for the biotech industry than *Myriad* because it relates to the validity of patents that claim diagnostic gene tests, not just isolated genes. In this case, the Supreme Court has agreed to review

lower court decisions on the patentability of business methods (*In re Bilski*).

In *Bilski*, patent claims involving a method of hedging risks in commodities trading were rejected by the U.S. Patent and Trademark Office on the grounds that “the invention is not implemented on a specific apparatus and merely manipulates [an] abstract idea and solves a purely mathematical problem without any limitation to a practical application.”

Although the subject matter in *Bilski* appears to share little in common with diagnostic gene patents, the legal question—whether inventions such as algorithms constitute patentable subject matter in method patents—is the same. In *Bilski*, the Federal Circuit held that Bilski’s method patent claim was ineligible

because it only claimed a useful result and did not “transform any article to a different state or thing” (the so-called “machine or transformation rule”). Similarly, diagnostic gene patents involve claims to a useful result, typically involving

methods of correlating specific genes or gene sequences with the presence or absence of disease. Thus, some may argue that gene diagnostics cannot be patented because there is no transformation of an article to a different state or thing. Accordingly, the Supreme Court’s ruling and characterization of the

Federal Circuit’s “machine or transformation” rule may call into question the validity of many already-issued diagnostic gene patents, and could reshape the way biotechnology and diagnostic companies protect their intellectual property.

The patent system was founded on the premise that patents provide incentives for economically-efficient research and development by providing a reward for innovation. A patent holder puts a scientific advance into the public domain in exchange for receiving a time-limited monopoly. Many biotechnology companies rely on patent protection to obtain investment and protect their technology while their products are under development or under FDA review. Without patents, research and development spending by biotechnology companies would likely be significantly reduced or eliminated altogether, thereby limiting the possibility of technological advances or breakthroughs. If the plaintiffs in the *Myriad* suit are successful and/or the *Bilski* patent claim is denied, the impact on biotechnology and personalized medicine could be huge.

The views expressed in this article are the views of the authors and do not necessarily represent the views of the Personalized Medicine Coalition and/or any of its members and/or sponsors; or the law firm of Townsend and Townsend and Crew and/or any of its clients. This article is for general information purposes only and should not be regarded as legal advice or opinion.



Genes have been considered patentable subject matter since a 1980 landmark Supreme Court case.

Harvard Meeting to Show Growth of Personalized Medicine

THE GROWING USE OF PERSONALIZED MEDICINE PRODUCTS AND approaches in healthcare and the ways in which new government and business policies are expected to affect personalized medicine will be explored at a conference in Boston November 18 and 19.

Top government, academic, and business leaders will speak at the conference, “Personalized Medicine: The Time is Now,” the fifth annual conference of the **Partners HealthCare Center for Personalized Genetic Medicine**, hosted by Harvard Medical School and Harvard Business School in collaboration with PMC. PMC will hold a reception at the Commonwealth Hotel November 17 to kick off the conference.

The conference aims to correct a misconception held by many health professionals that personalized medicine is something that will happen in the future, said Raju Kucherlapati, Ph.D., of Harvard Medical School, who is Chair of the conference organizing committee.

“Personalized medicine is going to be an important component of overall healthcare reform,” he said. “Personalized medicine is here now, and it will result in better outcomes for patients at no increased cost. We all need to learn now to incorporate it wisely into healthcare.”

The conference comes as Congress and the administration are expected to act on an ambitious plan to overhaul the nation’s health system. Meanwhile, the federal government is already taking steps to support health information technology and to develop a method for comparing the effectiveness of different medications, two key facets of health care as it relates to personalized medicine.

Health and Human Services Secretary Kathleen Sebelius has been invited to speak about the government’s role in personalized medicine. A separate panel of government and congressional speakers will discuss the role personalized medicine will play in a new healthcare system.

Confirmed speakers include Sir Michael Rawlins, Chairman of the United Kingdom’s National Institute for Health and Clinical Excellence, which among other things compares the effectiveness of different medications and treatments and advises the UK’s national health insurance program.

Samuel Aronson, executive director of information technology at Partners, will lead a discussion on health information technology and the impact of \$20 billion in federal spending. He will be joined by Abdul Bengali, Chair of Information Technology at the **Mayo Clinic**, and Philip C.M. Ma, Ph.D., a partner at McKinsey & Company, Inc.

A session on success stories in personalized medicine will be led by Lawrence Lesko, Ph.D., Director of Clinical Pharmacology at the Center for Drug Evaluation and Research at the Food and Drug Administration. Other sessions will cover the perspectives of payers and self-insured employers, new business models, and case studies on products related to personalized medicine, led by Richard Hamermesh, D.B.A., of the Harvard Business School.

A highlight of the conference will be the presentation of PMC’s annual 2009 Leadership in Personalized Medicine Award at a luncheon on November 18, followed by a speech from the honoree. The annual award recognizes the contributions of a visionary individual whose work in science, business or policy has advanced personalized medicine. Previous winners have included former Health and Human Services Secretary Michael Leavitt and Ralph Snyderman, M.D., Chancellor Emeritus at **Duke University** and Founder and Chairman of **Proventys, Inc.** The conference will be held at the Joseph B. Martin Conference Center at Harvard Medical School, 77 Avenue Louis Pasteur, Boston, Mass. To register for the meeting, go to www.personalizedmedicineconference.org.



Panelists discuss the impact of personalized medicine on medical practice during a panel during last year’s conference at the Harvard Medical School.

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www.personalizedmedicinecoalition.org/newinfo**

New Program Dispenses Personalized Medicine Diagnostics, Educates Doctors and Public

IN A LANDMARK MOVE THAT could help reshape thinking about how drugs are prescribed in the future, **Medco Health Solutions**, which dispenses medications to one-fifth of the American public, has created a program that seeks to improve patient care by requiring genetic tests to determine the correct dose of some medicines.

“Medco is translating the emerging science of pharmacogenomics into everyday clinical practice,” said Felix Frueh, Ph.D., Vice President, Research & Development, Personalized Medicine, at Medco. “We’re advancing pharmacy care to help remove the trial and error in medicine and provide tangible benefits for our 60 million members.”

Medco, which advises doctors and pharmacies about the medications it dispenses, says it faces a challenge in making physicians more aware of genetic testing. While nearly all doctors say genetic profiles may affect responses to therapy, most know little about genetic tests, according to a 2008 survey Medco conducted with the American Medical Association. Through a national ad campaign on key issues in healthcare reform, Medco is also helping to educate the public about the principles of personalized medicine.

Genetic testing could eventually involve a large number of medications and has the potential to whittle down the \$214 billion the U.S. annually spends on prescription drugs while improving their effectiveness,

Medco executives said.

“I’m a great believer in the future of personalized medicine,” said Robert Epstein, M.D., Medco’s Chief Medical Officer.

The new Personalized Medicine Program fits into Medco’s strategy of making therapies more affordable and higher quality, said J. Russell Teagarden, Medco’s Vice President of Clinical Practices & Therapeutics. “Personalized medicine has the potential to make drug therapies safer, more effective, more efficient and less expensive,” he said.

The company began its program last year with genetic tests for two drugs: tamoxifen, a breast cancer treatment, and warfarin, a blood thinner.

Later this year, Medco plans to launch two additional personalized-medicine products and plans to add a second oncology-related product in 2010.

Medco is continuing to research possibilities for incorporating genetic testing and other personalized medicine approaches into dispensing medications, Dr. Frueh said.

Under its Personalized Medicine program, Medco tests patients for the enzyme CYP2D6. The enzyme determines how well a patient metabolizes the drug. Knowing how well a patient metabolizes tamoxifen and whether they would likely benefit from treatment allows the physician to prescribe a more precise dose or an alternative medication, minimizing the patient’s exposure to side effects and making treatment more effective.

Medco also has a genetic test for sensitivity to warfarin, the second leading cause, after insulin, of adverse health outcomes in

emergency rooms, according to the Food and Drug Administration. As with tamoxifen, determining how a patient metabolizes warfarin can guide the physician in determining the right dose.

Medco has leaped ahead of other providers by adopting genetic testing even though the answers the tests provides aren’t always definitive. Rather, they may help healthcare professionals make better informed decisions to increase the likelihood of therapeutic success or reduce the likelihood of an adverse event.

The biggest barrier to implementing personalized medicine, Dr. Frueh said in an interview published in the July issue of *Personalized Medicine*, is that

the health profession has unreasonably high expectations for it. “We know that many drugs do not always work the way they are supposed to, and while we are trying to optimize their use, we literally let the ‘perfect’ become the enemy of the good,” he said. A good example is warfarin, he added. Medco’s genetic test doesn’t determine the exact size of a dose but alerts the physician that a higher or lower starting dose may be appropriate for a particular patient. Medco is certain that physicians will find that information useful in prescribing warfarin for certain patients, he said.

“Based on our knowledge today, I sincerely doubt that even the hardest critic of genetic testing would be willing to take a full dose of warfarin knowing she or she is highly sensitive (e.g., a CYP2C9 poor metabolizer) to warfarin. Case closed,” he said.

The Personalized Medicine Program is one of Medco’s fastest-growing programs, according to Teresa DeLuca, M.D., Vice President of Personalized Medicine Business Solutions at Medco. In little more than a year, 154 clients, covering about 6 million

“I’m a great believer in the future of personalized medicine.”

Robert Epstein, M.D.

“Medco is translating the emerging science of pharmacogenomics into everyday clinical practice.”

Felix Frueh, Ph.D.

people, have enrolled in tamoxifen and/or warfarin testing as part of their prescription benefit programs.

In May 2008, Medco surveyed 700 clients on their priorities related to pharmacy benefits. Pharmacogenomics was second on the list, tied with concern about overuse of medications. It took precedent over other emerging trends in science and cost reduction strategies. (Clients listed the formation of new benefit designs as their top concern.)

Medco is presenting its Personalized Medicine Program through symposia and client meetings. "Medco's pharmacogenomics message is resonating with clients," said Dr. DeLuca. "Clients are so confident these programs work, they're paying for the genetic tests."

Medco has had to work overtime to meet client demand, said DeLuca. "Our clients want more products and they want them yesterday."

In fact, the company moved up its planned launch of both its warfarin and tamoxifen programs after two research projects drew a strong positive response from clients. Medco had been studying the effectiveness of genetic testing for warfarin in partnership with the **Mayo Clinic** and had a separate study underway on tamoxifen with **LabCorp**. It launched commercial programs for both tests in May 2008.

Medco, a publicly traded company with over 22,000 employees, provides pharmacy services for private and public employers, health plans, labor union and government agencies, as well as for individuals served by Medicare Part D prescription drug plans. In 2008, Medco dispensed 105.8 million prescription drugs. 

Through a national ad campaign on key issues in healthcare reform, Medco is helping to educate the public about the principles of personalized medicine.

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GIVING BREAST CANCER PATIENTS A DOSE OF THE RIGHT MEDICINE.

What could be more important to the nearly 200,000 women who could be diagnosed with breast cancer this year than knowing the medication they're taking is actually working? Medco and Indiana University are working with patients to determine why certain women have recurrent breast cancer even though they are taking commonly used preventative therapies. Early results

suggest that some women either can't break down drugs well or take a second drug that blocks the needed metabolism, putting them at increased risk. Medco specialist pharmacists are working today to help guide physicians and patients to the right treatment based on medications and genetic makeup.

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If genetic testing was integrated into warfarin therapy, it is estimated that there could be \$1.1 billion annual reduction in healthcare spending.

When physicians prescribe the blood thinner warfarin, they have to adjust dosages until they achieve the proper levels. Medco is participating in a landmark study that may show how knowing your personal ability to break down warfarin can help you get the right dose and reduce bleeds and clots and may reduce trial and error. So to those looking to identify best practices that enhance the quality and value of healthcare, Medco believes it's

not about spending more, but spending smarter. Because smarter simply makes healthcare better. Join the conversation at makingmedicinesmarter.org

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JOSEPH B. MARTIN CONFERENCE CENTER
AT HARVARD MEDICAL SCHOOL, BOSTON

Partners HealthCare Center for Personalized Genetic Medicine will again partner with the Personalized Medicine Coalition and Harvard Business School to present its fifth annual conference on Personalized Medicine. This year's conference will highlight the current clinical impact of personalized medicine as it enters the healthcare delivery system. Widely considered the premier event in the field, the conference attracts national and international thought leaders as speakers, panelists and attendees.



2009 SPEAKERS/PANELISTS WILL INCLUDE:

Noubar Afeyan, Ph.D.
Flagship Ventures

Samuel Aronson
Partners HealthCare

Alison Ayers
Pfizer

Troyen Brennan, M.D.
CVS Caremark

G. Steven Burrill
Burrill & Company

Susan Dentzer
Health Affairs

Frank Douglas, Ph.D., M.D.
PureTech Ventures

Jon Friedenberg
El Camino Hospital

Gary Gottlieb, M.D., M.B.A.
Brigham and Women's Hospital

Daniel Haber, M.D., Ph.D.
Massachusetts General Hospital

Richard Hamermesh, D.B.A.
Harvard Business School

Arlene Hughes, Ph.D.
GlaxoSmithKline

David King
Laboratories of America
Corporation

Lawrence Lesko, Ph.D.
Food and Drug Administration

Mark Levin
Third Rock Ventures

Philip Ma, Ph.D.
McKinsey & Company

Lee Newcomer, M.D.
United Health Group

Sir Michael Rawlins
NICE

Eiry Roberts, MB, BS, MRCP, FFPM
Eli Lilly & Company

Marc Sabatine, M.D.
Harvard Medical School

Vance Vanier, M.D.
Navigenics

Jay Wohlgemuth, M.D.
Quest Diagnostics

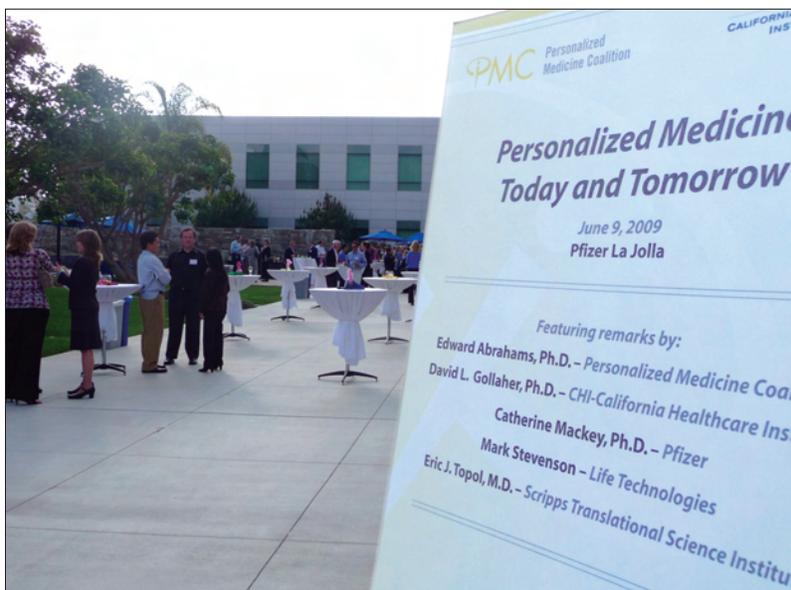
To register, please visit: www.personalizedmedicineconference.org

Members Mingle at PMC Receptions

THE PERSONALIZED Medicine Coalition reached out to local members and provided an update on recent developments in policy and practice on personalized medicine, its future, and its current application at two receptions on opposite sides of the country.

The events gave PMC opportunities to publicly showcase PMC's *The Case for Personalized Medicine*, its signature document, while leaders in the field discussed and examined personalized medicine from various viewpoints.

In May, PMC cosponsored an all-day conference with the North Carolina Biotechnology Center at their facilities outside Raleigh-Durham, North Carolina. Ralph Snyderman, Chancellor Emeritus of **Duke University** Medical System, gave the keynote address at the event, "Personalized Medicine in North Carolina: Innovation to Application."



PMC Members gather on the terrace at Pfizer's La Jolla, Calif., facility in June for PMC's reception and presentations on the current state of personalized medicine.

Morning sessions featured a discussion of industry case studies in personalized medicine, moderated by Michael Stocum, managing director of **Personalized Medicine Partners, LLC**. In the afternoon, panelists discussed how

genomics had been translated into healthcare in North Carolina at sessions moderated by Geoffrey S. Ginsburg, M.D., Ph.D., Director of the Center for Genomic Medicine at the **Duke Institute for Genome Sciences & Public Policy**, and a PMC Board member.

In June, the PMC and the California Healthcare Institute (CHI) hosted a reception at Pfizer La Jolla in San Diego titled "Personalized Medicine Today and Tomorrow." Among the speakers were Catherine Mackey, Ph.D., Senior Vice President of **Pfizer Global Research and Development**; Mark Stevenson, President and COO of **Life Technologies**; and Eric J. Topol, M.D., Director of the **Scripps Translational Science Institute**.

The next community event is scheduled for November 17 in Boston.

Susan Kahan

New Members

| | |
|--------------------------------------|--|
| Allegro Diagnostics | IDA Ireland |
| Biodesix | Institute for Individualized Medicine |
| BioStat Solutions, Inc. | L.E.K. Consulting |
| Cabernet Pharmaceuticals, Inc. | McDermott Will & Emery LLP |
| Celera | Scripps Health |
| Children's Mercy Hospitals & Clinics | SomaLogic, Inc. |
| College of American Pathologists | TcLand Expression |
| DxS Limited | University of Rochester |
| Generation Health, Inc. | Valerie August & Associates, LLC-Biotechnology Recruiter |
| Genoptix Medical Laboratory | William Blair & Company |

DXcon09west

DxCon09West

Personalizing Medicine through Diagnostics

September 29-30, 2009
Mission Bay Conference Center
San Francisco, CA

The Diagnostic Conference will bring together thought leaders and personalized medicine executives from leading diagnostic companies to focus on current challenges and subsequent opportunities for launching a diagnostic test in the US marketplace.

Please visit www.dxconference.com for more information and to register.



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 OSU Comprehensive Cancer Center -
 James Cancer Hospital and Solove Research Institute
 OSU Center for Clinical and Translational Science
 Personalized Medicine Coalition



Ohio State's Second Annual Personalized Health Care National Conference
Transforming Health Care through Personalized Medicine

Join Leroy Hood, MD, PhD, Ralph Snyderman, MD, and a host of academic leaders, industry experts, government policy makers, and healthcare providers from around the nation to discuss innovations in personalized medicine research and the role of academic medical centers in translating these findings into a value-based, patient-centric healthcare system. For more information or to register please visit www.cphc.osu.edu.

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The rapid pace of scientific discovery in the life sciences, coupled with the ability to process and analyze enormous amounts of information, have combined to create a "perfect

storm" of knowledge discovery that in time will give rise to more effective therapies to treat existing disease. Personalized medicine could also lead to earlier diagnosis of disease,

and an increasing ability to develop wellness and prevention solutions for health maintenance. Taken together, these have the power to transform healthcare as we know it.

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Union Relies on Genetics to Manage Patient Care

A SMALL UNION THAT PROVIDES INSURANCE for its members is focusing on personalized medicine to reduce costs and help members recover from chronic health problems or manage them more effectively. American Maritime Officers, a union whose members are captains and engineers of the U.S. Merchant Marine, receives payments from the shipping companies that hire its members so that it can cover their health-

For members with challenging health issues, the union has turned to personalized medicine.

care costs. Healthcare is a critical issue for the union, since members must report their medical condition in order to receive their licenses. The union oversees medical claims for 4,000 members and their families.

Health care has always posed a unique challenge for members of American Maritime Officers, who may be away at sea for six months at a time. They frequently

find themselves seeking care in a foreign port, half a world away from the doctor they see at home. At the same time, the largely sedentary lifestyle makes it easy to eat too much and exercise too little. In the past decade, more members became obese or diabetic, or had high blood pressure or cholesterol. Regardless of the increasingly costly care they received, more and more had chronic conditions.

"We're supposed to be a health plan," said Steve Nickerson, executive director of American Maritime Officers Plans, the union's insurance arm. "A health plan should be in the business of providing health."

The organization changed its strategy from overseeing claims to taking a more active role in its members' health. Under the direction of Dr. Alvero O'Campo and Janet Davenport, R.N., manager of the union's health and wellness program, the union has helped members lose weight, lower their blood pressure and combat

other chronic problems through a two-week "Fit for Duty" program that employs a nutritionist and fitness expert to help them improve their eating and exercise habits.

For members with more challenging health issues, the union has turned to personalized medicine. Through the **Institute for Individualized Medicine**, it offers genetic testing to identify gene mutations that point to immunological, cardiovascular, bone, or environmental problems. Genetic testing "has become a tool for case management," Mr. Nickerson said.

Many in medicine criticize genetic tests as expensive and unnecessary, but Mr. Nickerson says he thinks they save money. The union has found that failure to understand the underlying cause of a condition or prescribe the correct medication the first time can wind up costing hundreds of thousands of dollars in extra charges.

Officers Plans does not yet have enough data to directly calculate any savings from genetic analysis, but since implementing the program two and a half years ago the health plan's overall costs have increased less than 1 percent, Mr. Nickerson said, compared to nearly double-digit increases in medical costs for most employers.

"Genetic testing has become a tool for case management."

Steve Nickerson

In helping its members navigate the healthcare system, the union also advocates for genetic testing in the larger medical community. It has intervened with doctors to ask them to prescribe the Oncotype Dx breast cancer test, among others. Ms. Davenport, the wellness director, says that while some insurers don't cover such tests, the union believes the tests help it provide the best care for its members and keep them well.

"Many doctors don't prescribe genetic tests because they think the patients' insurance won't cover it," Ms. Davenport said. "I tell them, we'll pay for it. Now that genomics has come along, I can't imagine doing anything else. Why take a medication that doesn't work for you?"

Elizabeth Schwinn



Janet Davenport, R.N.



The American Maritime Officers offers health education and genetic testing for members with chronic health issues at this training facility in Dania Beach, Florida, in addition to work-related simulation and training.

From the Executive Director

continued from page 1

simply, as medicine.

From their perch at the Harvard Business School, Clayton M. Christensen and his colleagues, Jerome H. Grossman and Jason Hwang, have written a new book, *The Innovator's Prescription: A Disruptive Solution for Healthcare* (McGraw Hill, 2009) that calls for speeding up the process by allowing the market to work its magic. The book assumes that personalized medicine represents a better model for healthcare, and outlines how it can lead to higher quality, lower costs, and greater accessibility (the holy grail of healthcare reform) if we follow what some would say are their radical recommendations.

Christensen is one of the world's leading authorities on innovation in business. The author or co-author of five previous books including the national bestseller, *The Innovator's Dilemma*, he has elegantly demonstrated how innovation can upend entrenched industries and also benefit the public. He has shown, for example, how personal computer makers turned the computer industry upside down by introducing low cost, low quality, but easy-to-use machines that over time drove most of the mainframe companies into bankruptcy because their business models and large overhead costs would not allow them to adapt to the new competition.

He sees a pattern of disruption that transforms industries across all sectors. First, a "simplifying technology" is introduced that decreases the amount of skill necessary to solve a problem; second, new networks based on the new technology are developed that deliver services more efficiently and at decreased cost; and third, a new "value network" built around supportive systems to facilitate the new paradigm emerges and the expensive, inefficient status quo is replaced by one that serves the public's interest in obtaining lower cost,

higher quality products and services.

The Innovator's Prescription maintains that healthcare is no different from other industries.

Christensen notes that in 2007 healthcare accounted for 16 percent of the United States' GDP, up from 7 percent in 1970. According to him, this unsustainable trend threatens the nation's economic future. "We are," he writes, "in big trouble" because "a runaway reactor called fee-for-service reimbursement" fuels the healthcare system's escalating costs. (It is worth noting that few elected officials propose jettisoning fee-for-service reimbursement in the current healthcare debate.)

Nevertheless, Christensen is optimistic because he sees the same forces that have disrupted other industries at work in healthcare.

First, he argues that a technology-enabled disruption in healthcare now exists. He calls it "precision medicine," by which he means our improved ability to precisely diagnose and treat many diseases. While many may argue over the scope of this development, PMC agrees that it clearly points to better outcomes and lower costs.

Second, as precision medicine makes its way through the system, it will change the way medicine is practiced

and delivered. Expensive, highly trained specialists will be displaced by "value-added process businesses" that can solve problems for advertised, lower prices because they focus on rules-based evidence. Why go to the doctor for an earache, wait forever, and then get billed some astronomical amount when you can drop by your local MinuteClinic and get exactly the right, low-cost prescription because a molecular test has so informed a trained technician? We

will also see more value-added facilitated networks spring up like Kaiser Permanente and the **Mayo Clinic**, whose goal is to keep people well before they get sick -- at much less cost to the system and the patient.

Finally, healthcare reform that introduces market forces into physician and patient decision-making will help make medical care both less costly and more accessible.

Christensen rightly calls this a "coordinated revolution,"

and outlines policies to help advance it. These include revisiting how the National Institutes of Health funds research so that interdisciplinary work is encouraged; reimbursing for value rather than complexity; encouraging pharmaceutical companies to conduct trials according to the molecular definition of disease and thereby tailor their drugs to the right patients; and putting in place a regulatory system that promotes innovation.

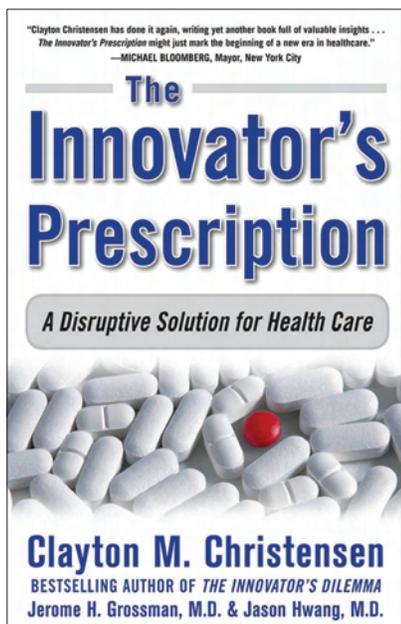
Most of these are very good ideas and indeed are part of the PMC's agenda. Some readers may ask, though, if healthcare is just another business, or if there are not in fact other forces and values at work that should govern medicine. Chief among these forces is the belief that access to the best available healthcare is a fundamental right, along with life, liberty, and the pursuit of happiness. Few insured people, for example, will accept a system that does not permit them to choose their own doctors or to access the care they think they need when they need it.

As the nation's leading proponent of healthcare reform, President Obama has said many times, "If you like your doctor, you will be able to keep your doctor, period. If you like your health plan, you'll be able to keep your health plan, period. No one will take it away, no matter what."

Given that most people prefer stability to disruption and that they will use the political system to help them protect that preference, evolutionary change may be the better prescription for what ails us.

"The health-care industry needs to be disrupted."

Clayton M. Christensen



Edward Abrahams
Executive Director

PMC Seeks to Clear Up Confusion Over Direct-to-Consumer Genetic Testing

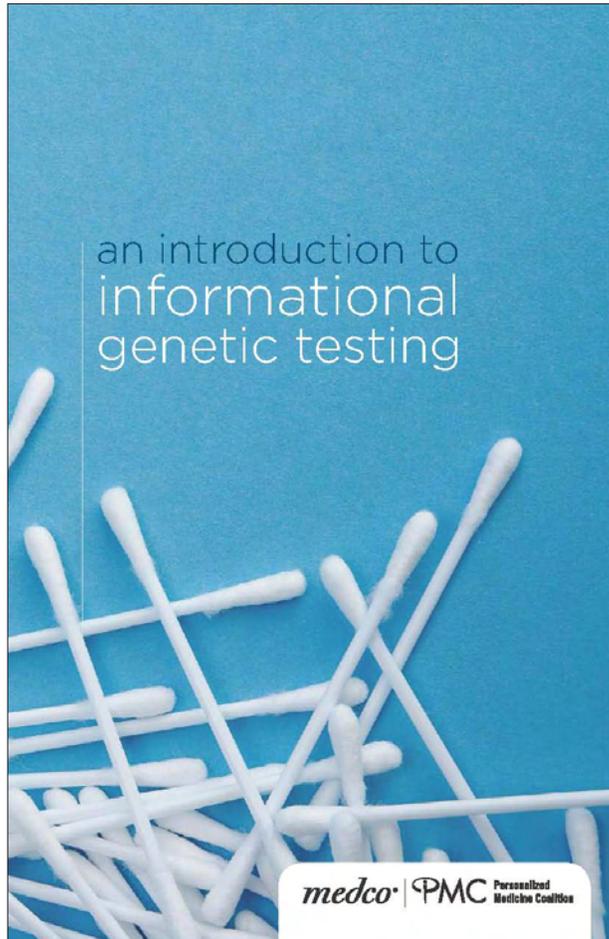
THE FEDERAL GOVERNMENT undertook to map the human genome 20 years ago at a total cost of roughly \$3 billion. Today, a complete genome sequence can be had for only \$48,000 from **Illumina**, a developer and manufacturer of genetic tools based in San Diego, Calif. Meanwhile, other companies, like **23andMe**, **deCODE**, and **Navigenics** offer to assess portions of an individual's genetic code for between \$400 and \$2500.

The remarkable decline in prices for genetic sequencing and the resulting ability of average Americans to gain access to information about their personal genetic makeup has raised questions for both consumers and government agencies. Some critics of consumer genomics, including officials at the Food and Drug Administration and the Centers for Disease Control, argue that the tests are not consistent in their ability to predict risk, that they lack clinical relevance, and that they pose ethical challenges by providing information directly to consumers, who may not understand its significance.

At the same time, consumer genomics has captured the attention of the media and the public, making it a highly visible aspect of personalized medicine, and spurring the Personalized Medicine Coalition to try to clear up some of the confusion and criticism.

PMC sought consensus on consumer genomics among proponents of personalized medicine, and also saw an opportunity to teach consumers how the new tools can be wisely integrated into healthcare.

PMC encouraged consumer genomics companies to develop a consensus on common scientific standards so that consumers



This 8-page brochure, produced jointly by PMC and Medco, is available from PMC's website. Members may also request hard copies of the document.

would be able to get the same answers to the same questions, even though each company might present the results differently. The effort has eliminated some of the confusion that had threatened to undermine the public's perception of the tests. However, work remains to be done, such as defining which biomarkers should be part of the analysis of a specific predisposition.

PMC also organized a roundtable in Washington, DC, with the support of the consumer genomics companies, to allow patient advocacy groups to express their concerns about consumer genomics. The advocacy groups said they wanted a guide to help them understand basics about the tests, such as the differences between informational genetic tests and those that might be ordered by a doctor, what information the tests provide, and whether they are covered by health insurance. In response, the PMC has published an eight-page primer on the subject with the support of **Medco**. *An Introduction to Informational Genetic Testing* is a guide to help consumers understand not only what genetic testing is, but also what to do with the results of a test.

The brochure, which was released at a Boston consumer genetics conference in June, explains the difference between medical and informational genetic testing and their uses. It also addresses concerns such as the privacy of genetic information and the advisability of working with a genetic counselor. A copy of the brochure is available on PMC's website at <http://www.personalizedmedicinecoalition.org/objects/pdfs/Guide-to-Info-Genetic-Testing.pdf>. Hard copies may also be obtained upon request.

Edward Abrahams



Personalized Medicine

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Free Subscription for PMC Members

PMC in the Press

In discussing the nomination of Francis Collins to head the National Institutes of Health, **The Wall Street Journal's** Health Blog quotes the Personalized Medicine Coalition's statement supporting the nomination. **GenomeWeb** quotes PMC board member Patrick Terry, President and Founder of **Technic Solutions, LLC**: "His communication and leadership abilities will facilitate innovative approaches to biomedical research and the advancement of personalized medicine."

U.S. News and World Report published an interview with PMC executive director Edward Abrahams in July 2009 on the future of personalized medicine. The interview covered topics including the different treatments personalized medicine has made possible, the scientific hurdles related to personalized medicine, the need for the government to invest more in research on personalized medicine and development of genetic tests of biomarkers.

In the July 2009 edition of **Clinical Laboratory News**, produced by the **American Association for Clinical Chemistry (AACC)**, Edward Abrahams, executive director of the Personalized Medicine Coalition, talked about personalized medicine skeptics in an article on AACC's principles for healthcare reform. He cites real-world examples of the benefits of personalized medicine in PMC's signature document, *The Case for Personalized Medicine*.

The Journal of Diabetes Science and Technology published a July 2009 article written by PMC executive director Edward Abrahams, and Mike Silver of Synaptix Communications entitled, *The Case for Personalized Medicine*, excerpted from PMC's signature document. They explain that personalized medicine brings added precision to healthcare with more emphasis on preventative and effective approaches.

GenomeWeb Daily News reported in June on a bill introduced by Senators Max Baucus (D-MT) and Kent Conrad (D-ND) on comparative effectiveness research that places more emphasis on personalized medicine than did last year's version of the bill. PMC public policy director Amy Miller said PMC is excited that personalized medicine has become part of the debate on health care reform. The bill includes language on genomics and diagnostic testing.

In an article on the future of personalized medicine in June, **Drug Discovery & Development** looked at the ongoing debate on the utility of identifying genetic risks and causes of common diseases.

Edward Abrahams, PMC's executive director, discussed the overall value of personalized medicine. Paul Stoffels, M.D., Group Chairman of **Johnson & Johnson Pharmaceutical Research & Development**, told the magazine that personalized medicine allows for greater development in drug discoveries and research.

The New York Times on May 5 reported that Medicare will not pay for genetic tests that will aid doctors in distinguishing the best dose of the blood thinner warfarin for a particular patient, although it may approve the tests in the future. The Centers for Medicare and Medicaid Services said there was not yet enough evidence that the tests improved patients' health, but that it would

revisit the decision as more evidence accumulates. Edward Abrahams, executive director of PMC, said the expensive trials required by Medicare might be unreasonable for some diagnostic tests. The article noted that PMC advocates genetic testing. Medical societies are divided on the warfarin testing issue, the paper said.

BioCentury cited PMC's *Case for Personalized Medicine* in an article in May on the future of the diagnostics industry and personalized medicine. Genetic screening tests that are intended to predict a person's response to a treatment are not uniformly covered by insurers, and the Centers for Medicare and Medicaid Services (CMS) interprets the law to preclude most genetic screening tests from reimbursement. However, this could change in future decisions as the agency places increased emphasis on preventative medicine.



The Pink Sheet reported in April that private stakeholders sent a clear message to the Federal Coordinating Council for Comparative Effectiveness Research at its meeting that they want more representation in comparative effectiveness research. They also told the council that comparative effectiveness research must not seek a "one-size-fits-all" solution to treating a health condition. PMC public policy director Amy Miller said there is a need to incorporate personalized medicine concepts and technologies for better healthcare research.

InsideHealthPolicy reported on the Senate bill on comparative effectiveness research that includes PMC's recommendations to help further personalized medicine. Amy Miller, PMC's public policy director, said the Senate bill is more focused on personalized medicine research than is the bill proposed by the House Democrats.