

The Personalized Medicine Coalition, representing scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system.

Spring | 2011

## PMC Hosts Conference Highlighting Cardiovascular Applications of Personalized Medicine

Personalized medicine is playing an increasing role in treating heart disease and is likely to be more widely adopted as current research makes its way into treatment, according to a conference on cardiovascular medicine hosted by the Personalized Medicine Coalition.

The conference, *New Frontiers in Personalized Medicine: Cardiovascular Research and Clinical Care*, organized at the suggestion of the National Heart Lung and Blood Institute (NHLBI), provided a first-of-its-kind opportunity for stakeholders from academe, industry and government to highlight personalized medicine approaches that are beginning

to improve care for the 81 million patients with cardiovascular disease in the United States and to share new research to personalize cardiovascular care in the near future.

Speakers identified several personalized therapies for heart disease, discussed a growing body of research, and explored the federal government's efforts to solve some of the basic questions about personalized medicine and heart therapy.

Among the personalized medicine therapies in use today are a less-invasive approach to heart biopsies, a new treatment for rare heart rhythm

*continued on page 4*



Keynote speaker Victor J. Dzau, M.D., discusses hurdles to the adoption of personalized medicine.

### INSIDE:

PMC Cardiovascular Conference .....	1
From the President .....	1
Policy Update .....	2
Policy Brief .....	3
Opinion: A Dying Wish .....	5
HIT Standards Will Promote PM .....	6
Cancer Care: A Model for Personalized Medicine .....	7
Molecular Diagnostics: Medical Community Eager to Learn More .....	8
PMC Announces New Board Members .....	11
PMC in the Press .....	12

### FROM THE PRESIDENT



### Adriana Jenkins' 'A Dying Wish'

BY EDWARD ABRAHAMS

When Dorothy Parker asked Ernest Hemingway in 1929 what he meant by "guts," he famously responded, "Courage is grace under pressure."

In my experience, no one has demonstrated more grace under pressure than Adriana Jenkins, who died February 9th.

Her opinion piece, "A Dying Wish," published posthumously in *Forbes*, is reprinted in these pages.

Only ten days before she died, Adriana sent us her essay for possible publication in our newsletter. Recognizing the power of her argument and the centrality of her message to PMC's mission, we told her that PMC would be honored to include it. We were even happier when she wrote us three days later, "I just got some tremendous news; *Forbes* is going to be publishing the piece."

*continued on page 10*

# POLICY UPDATE

## Study Confirms Pharmaceutical Industry's Commitment to Personalized Medicine

An increased number of personalized medicine products are in the drug pipelines of large pharmaceutical and biotechnology companies, according to a study released by the Tufts Center for the Study of Drug Development. Personalized medicine products comprise between 12 and 50 percent of current pipelines, said the 25 companies in the study, which was released last November. The study projected that investment in personalized medicine product development would increase by an average of 53 percent over the next five years.

## Issue Brief Highlights Need for Update of Reimbursement System

A discord exists between the rapidly increasing number and therapeutic power of personalized medicine diagnostics (PMDs) and a payment system that does not recognize their clinical utility or economic value, according to an issue brief released in December by the Personalized Medicine Coalition and **Boston Healthcare Associates**.

The brief, *The Adverse Impact of the US Reimbursement System on the Development and Adoption of Personalized Medicine Diagnostics*, outlines systemic problems facing reimbursement for PMDs. "Because appropriate reimbursement results from a complex interplay of codes, coverage decisions, policies, and payment amounts, addressing any of these aspects individually is inadequate. Instead, obtaining the full benefits of PMDs will require a fundamentally different reimbursement paradigm," writes report author David Parker, Ph.D., Vice President of Boston Healthcare Associates.

The issue brief was the product of a working group that met during the summer of 2010 to focus on Medicare reimbursement issues. The working group, co-chaired by Scott Allocco of **BioMarker Strategies** and Steve Phillips of **Johnson & Johnson**, included representatives from more than 30 diverse PMC member organizations. The issue brief is available for download at <http://www.personalizedmedicinecoalition.org/>.

## PCORI Methodology Committee Lacks Private-Sector PM Expert

The Government Accountability Office (GAO) announced the members of the Methodology Committee for the Patient Centered Outcomes Research Institute (PCORI) in January. PMC was disappointed to see that none of the private sector members bring expertise in personalized medicine, particularly since the statute specifically identified experts in genomics as necessary to the Methodology Committee function.

In October, PMC submitted a letter to GAO nominating ten experts in personalized medicine from across academia and industry.

Subsequent to the Methodology Committee's selection, PMC recommended that the PCORI Board of Governors create an ad hoc advisory panel focused on personalized medicine and innovation to ensure that genomic and other personalized medicine considerations are addressed in the development of research methods and priorities.

## FDA Releases Draft Pharmacogenomics Guidance

The Food and Drug Administration (FDA) in February released draft guidance on the early use of genomic data in clinical studies.

The draft guidance, *Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies*, stresses that getting genomic information for all trial subjects during early development will make it easier to identify clinically-important genomic differences later in the process. Ideally, the draft guidance says, consent for DNA collection should be obtained from all participants when they are enrolled, to avoid bias that might result from delayed collection. It also suggests considering known pharmacogenomic factors during preclinical assessment, and notes that pharmacogenomic factors for assessing interindividual variability can be integrated into prospective clinical pharmacology studies. For more information or to submit comments, which are due by April 19, 2011, visit <http://federalregister.gov/a/2011-3679>.

## New Members to the Personalized Medicine Coalition

Asterand  
Beaufort, LLC  
Bionest Partners  
Bioscience Valuation BSV GmbH  
Cardiovascular Research Center/Mount Sinai School of Medicine  
Catholic Health Initiative's Center for Translational Research  
CryerHealth  
Entelos  
Fairbanks Institute for Healthy Communities

Fly Life Spa.  
Foundation Medicine, Inc.  
GE Healthcare  
GenomeQuest, Inc.  
GHC Genetics Ltd.  
Informed Medical Decisions, Inc.  
Institute for Systems Biology  
Institute for Translational Oncology Research (ITOR)  
Integrated Diagnostics  
International Cancer Advocacy Network ("ICAN")

Malignant Hyperthermia Association of the US  
Merck  
MIT Center for Biomedical Innovation (CBI)  
Multiple Myeloma Research Foundation  
Neogenix Oncology Inc.  
Pamlab, LLC  
Raabe College of Pharmacy  
Robinson, Bradshaw & Hinson  
Russell Reynolds Associates  
Selventa  
Stanford University School of Medicine



## Challenges and Opportunities Lie Ahead for Personalized Medicine Policy

BY AMY MILLER | PUBLIC POLICY DIRECTOR

President Obama recently asserted that the Food and Drug Administration's (FDA) regulatory models were designed for the types of medical devices seen in museums. He called for strategic thinking about how regulations could both respond to and stimulate the development of innovative products. Personalized medicine product innovators have long asserted what the president announced: the current regulatory system presents an unnecessarily high barrier to bringing new products to the market.

The Personalized Medicine Coalition advocates for priority review or an accelerated process for personalized medicine products at FDA. We also argue that business-model barriers could be overcome if, for example, patents were extended for personalized medicine products, as they are for orphan drugs.

The legislative environment this year and next challenge us to think creatively about how to best make the case for personalized medicine. As battles over the federal budget illustrate, a Republican-led House and Democratic-led Senate create a difficult environment for advocates of new health care legislation, especially given the deficit-reduction focus of new Tea Party-backed Republicans. Nevertheless, Congress must reauthorize FDA device and drug user fees in 2012, which may provide an opportunity to enact health care legislation.

As a result, this year PMC's policy agenda will build on previous work and take advantage of the administration's increased focus on innovation as a means to job growth and economic development. Central to our work is educating policymakers about personalized medicine, as well as developing champions for its adoption in the executive and legislative branches. We will also continue to promote

personalized medicine through a series of timely events and commissioned papers that outline and analyze solutions to the problems facing innovators, researchers, clinicians, and payers.

Below are the projects under development.

### Capitol Hill Briefing

Health care reform raised the profile of personalized medicine among members of Congress. Some asked PMC to organize a "Personalized Medicine 101" briefing on Capitol Hill. We have invited Representative Anna Eshoo, D-Calif., who represents Silicon Valley, to sponsor the event, and hope that the briefing will inform her redrafting of the Genomics and Personalized Medicine Act (GPMA) so that the bill introduced this Congress contains additional provisions designed to enable personalized medicine development and adoption.

### Incentives

Recognizing that creating incentives for personalized medicine products would stimulate both investment and innovation, we will continue to advocate for research and development tax credits, a streamlined path for personalized medicine products through FDA, and patent extensions for these products. We will continue to work with our members to further develop a package of policy solutions designed to encourage investment in new personalized medicine technologies and reduce barriers to their adoption.

### FDA Summit

Individual sectors within PMC have developed different proposals for reforming FDA regulation of personalized medicine diagnostics. These suggestions can overlook co-developed drug-diagnostic combination products. To help

resolve this important issue, PMC, at the suggestion of FDA, will hold a summit to bring the agency together with drug, diagnostic, and lab service companies to openly discuss a taxonomy for risk categorization and evidence development for different personalized medicine products and services, and the regulatory framework drug-diagnostic products encounter at FDA.

### Reimbursement Reform

Last year, PMC published *The Adverse Impact of the US Reimbursement System on the Development and Adoption of Personalized Medicine Diagnostics*, a compendium of issues that personalized medicine products face at the Centers for Medicare and Medicaid Services (CMS). A separate paper also released last year, *The Reimbursement Landscape for Novel Diagnostics: Current Limitations, Real-World Impact, and Proposed Solutions*, funded by **Biotechnology Industry Organization (BIO)**

proposed a series of solutions to the reimbursement problems we outlined. To move forward we plan to partner with BIO to host an event where leaders from industry can discuss potential reimbursement policy solutions with public and private payers. We will also publish the proceedings of the meeting outlining the pros and cons of various solutions.

As a model for care, personalized medicine offers a way to improve health care outcomes and provide more value for every health care dollar. At a time when economic growth is needed, health care innovation can fuel the economic recovery by creating jobs and bringing products to market that lower health care costs. With this as our message, we have an opportunity to reconstruct the policy landscape for 21st-century products, not museum pieces.

# Conference Examines Personalized Cardiovascular Medicine

*continued from page 1*

disorders, and better-informed dosing recommendations for a widely-used blood thinner.

Panelists said that more personalized therapies will soon be available.

"The biggest, earliest advances will probably be in pharmacogenomics," said Richard Katz, M.D., conference co-chairman and a professor at **The George Washington University**.

The drive towards using pharmacogenomics in cardiovascular therapy is fueled by recent discoveries that some widely-used drugs aren't effective for everyone. The Food and Drug Administration (FDA) last year added a warning to Plavix® (clopidogrel), an antiplatelet drug, to alert doctors that some patients' genetic makeup may prevent them from metabolizing it.

Susan Shurin, M.D., Acting Director of NHLBI, told conferees that the era of personalized medicine calls for systems approaches to both biology and health care. NIH established the National Centers for Systems Biology in part to develop such an approach.

"To classify diseases in the 21<sup>st</sup> century, we'll need to use 'omics' and systems biology: expand genomic testing use to disease modeling rather than screening, and apply systems biology to foster translational research," she said.

In his keynote address, Victor Dzau, M.D., President and CEO, **Duke University** Health System and Chancellor for Health Affairs, Duke University, pointed to the absence of a major personalized heart therapy as a hurdle to widespread adoption of personalized medicine.

"There's no single application yet that is compelling enough to drive the building of the systems we need to perform these tests routinely, to collect data or tissue samples for future use," he noted. "Without such a mechanism, we lose the opportunity to harness economies of scale, such as running the entire genome sequences instead of a few SNPs."

Physicians may also resist even blockbuster applications unless they understand genomics, said Dr. Shurin.

"Cardiologists and general practitioners remain out of the loop, and it is time to define the value of pharmacogenetics-based therapies to guide them in selecting the most appropriate medication for their patients."

Only seven percent of cardiovascular patients are treated with personalized medicine, according to a survey presented at the conference by the American College of Cardiology (ACC).

There are several reasons why personalized care has not become as ubiquitous in cardiology as it is becoming in oncology, speakers said.



Michael Caldwell, M.D., Ph.D., Pierre Cassaigneul, Benjamin Salisbury, Ph.D., and Richard Katz, M.D., review available clinical applications of personalized cardiovascular medicine.

For one thing, cardiovascular care often requires decision-making under severe time constraints in order to save a patient's life, said conference co-chairman Jay Wohlgemuth, M.D., Vice President of Science and Innovation for **Quest Diagnostics** Nichols Institute.

Thus, a key barrier to clinical use of new personalized approaches is the difficulty of "delivering the diagnostic information in a time and place where it can affect a clinical decision," Dr. Wohlgemuth added.

Speaker John C. Lewin, M.D., ACC's Chief Executive Officer identified several hurdles to personalized cardiovascular care: "insurance coverage has not been established for many personalized medicine tests and treatments, often patients and doctors don't know about it, and physicians believe the science is lacking to support the assays."

Some speakers and conference participants disagreed over the amount and type of evidence that should be necessary for clinical adoption of a new test or therapy. Stephen Kimmel, M.D., an Associate Professor of Medicine at the University of Pennsylvania suggested that the only acceptable evidence is a randomized controlled clinical trial.

Russell Teagarden, Ph.D., Vice President of Scientific and Medical Affairs at **Medco Health Solutions, Inc.** questioned that view, citing an observational study released by the Medco Research Institute and the **Mayo Clinic**.

It found that hospitalization rates for patients taking warfarin (outside of academic health centers) dropped by approximately 30 percent when genetic information was available to prescribing physicians.

Dr. Teagarden said he hopes that medical experts will learn to derive value when they can improve quality and decrease costs.

"We'd know about efficacy from one study and effectiveness from another," he said. "In a sane world, we wouldn't have these kinds of arguments."

Dean Sproles, CEO and Chairman of **Iverson Genetic Diagnostics, Inc.**, which helped sponsor the conference and runs a nationwide study of hospital systems to assess the utility of genetic testing to set the initial warfarin dose, summed up the need for personalized medicine in cardiology: "It is about individualizing treatment to improve patient safety and outcomes, thereby reducing health care costs."

"The fact that we got NHLBI, FDA, AMA, GWU, the ACC and others together with the PMC to talk about the opportunities was itself pretty exciting," Dr. Lewin said. "There were a lot of new ideas discussed and valuable interactions between researchers and practitioners."

# A Dying Wish

BY ADRIANA JENKINS

I am dying. We will all die someday, but my expiration date is sooner than most. At age 41 I am facing my second recurrence of cancer. I was first diagnosed with an advanced and rare type of breast cancer in 2001. This led to a large tumor in my brain last year. Now the cancer has spread to my spinal fluid, which will likely seal my fate within weeks.

At my initial diagnosis I participated in a clinical trial evaluating Herceptin®, a so-called personalized medicine (PM) drug targeting a mutation believed to be driving my cancer.

**A targeted cancer drug kept me alive for nine years. Congress must ensure that future patients get the same chance to live.**

While most cancer drugs work by targeting mechanisms common to all cancers, such as cell division, PM drugs hit specific genetic mutations driving the cancer's spread. They typically come paired with a diagnostic test to select the subset of patients most likely to benefit. The idea is to get the right drug to the right patient. (I know about this because I've worked in biotech for 15 years.)

Herceptin® likely extended my life by at least nine years. It has had similar benefits for many thousands of patients around the world. It is an amazing example of how the health care industry can develop personalized cancer treatments.

But Herceptin®, invented at Genentech (now part of Roche), might never have made it to market if it had been tested on all breast cancer patients. The drug aims at the 25 percent of breast cancer patients whose tumors express high levels of a protein called HER2. Because Genentech tested the drug on this narrower subset of patients, the trials worked. Patients lived longer. Today Herceptin® has nearly \$6 billion in annual sales.

Despite Herceptin®'s success, the pharmaceutical industry seems loath to focus on developing other PM drugs, which often means reducing potential profits.

After spending \$1 billion over 15 years to develop a drug, companies are eager to recoup their money fast. The business side of the equation wants as many people to take the drug as possible, whether it's effective or not. I worked at a company whose CEO championed personalized

drugs in public statements. But its first product was not a PM drug. As a public company, it got too much pressure to become profitable for it to further reduce an already small patient population with a diagnostic test.

The result of the focus on testing cancer drugs on all patients is painful trial and error. Chemotherapy is prescribed with no guarantee of effectiveness and can cause wretched, and sometimes fatal, side effects. But cancer patients like me don't have time to waste. How do we convince drugmakers to focus their shrinking R&D budgets on this area of scientific discovery?

One idea is to create an incentive for drugmakers comparable to that in the Orphan Drug Act. Passed in 1983, it encourages companies to develop drugs for diseases that have a small market (fewer than 200,000 patients in the U.S.). Under the law, companies that develop such a drug may sell it without competition for seven years, in addition to often receiving quicker "fast track" regulatory review. This has become such a profitable pursuit that most drugmakers are pursuing at least one "orphan" drug.

A comparable law could push drugmakers to develop PM drugs for cancer and other deadly ailments. It could combine additional market exclusivity with assurance of accelerated regulatory review.

The Orphan Drug Act was passed only because of the support of the National Organization of Rare Diseases. I urge patients, physicians and insurers to create a similar group to support the commercialization of personalized cancer drugs.

I am so grateful for the extra time a PM drug gave me. My hope is that future patients have the same chance to benefit from personalized medicine.

*Adriana Jenkins, who died Feb. 9, was a publicist who represented more than a dozen biotech companies over a 15-year career. Her article, which first appeared in Forbes magazine on February 28, is reprinted with permission from the magazine.*



SEACIA PAVAO

**The result of the focus on testing cancer drugs on all patients is painful trial and error... cancer patients like me don't have time to waste.**

## HIT Standards Will Promote Personalized Medicine, Report Finds

Until the United States adopts standards for health information technology that promote connectivity, integration, and data analysis, it will gain far less than it might from its \$27 billion investment in creating a health information technology infrastructure according to a report released January 28 by the Brookings Institution.



Panelists Mark Boguski, M.D., Ph.D., Donald Rucker, M.D., Darrell West, Ph.D., Paul Billings, M.D., Ph.D., and Emad Rizk, M.D., discuss how HIT can better facilitate personalized medicine.

Through financial incentives, the government has made progress in persuading doctors, clinics and medical institutions to adopt sophisticated health information technology systems. However, government faces “deep challenges” in getting value for this investment and advancing personalized medicine unless it redefines the standards required for health information technology systems to qualify for federal monies, said Darrell West, Ph.D., author of the report, *Enabling Personalized Medicine Through Health Information Technology* and Director of Brookings’ Center for Technology Innovation.

The paper was released as the Obama administration continues to fund the adoption of health information technology, including electronic medical records, and on the eve of the announced resignation of David Blumenthal, M.D., National Coordinator for Health

Information Technology. At issue for personalized medicine advocates is whether those records will be detailed enough to incorporate genomic information and universal enough that the information can be aggregated and used for research purposes.

Digitizing health information will make it possible to integrate data

from medical claims, tests and clinical outcomes in the same way that the national drug coding system integrated the tracking of pharmaceuticals, he said. “When combined...this material will shorten evaluation cycles and enhance our ability to control costs in ways that do not weaken quality,” he said.

The paper also recommended substantial updates to the reimbursement and coding system to better differentiate between personalized medicine diagnostic tests, a conclusion PMC also reached in an issue brief entitled *The Adverse Impact of the US Reimbursement System on the Development and Adoption of Personalized Medicine Diagnostics*, released last year.

Speaking at a Brookings seminar on the subject, David Brailer, M.D., Ph.D., the former National Coordinator for Health Information Technology, noted that advocates for information technology have spent many years persuading the

medical world that HIT would benefit health care and that personalized medicine advocates can learn from that long struggle.

“When it came to the IT scene, the gurus talked in big words and long sentences,” he said. “Then they were frustrated that no one understood them.”

Now Chairman of Health Evolution Partners, a venture capital firm, Dr. Brailer underscored the need for a new reimbursement framework for personalized medicine products. The lack of that framework, he noted, “has had a more adverse effect than any other aspect on the development of these technologies.”

Dr. West moderated a panel discussion of his paper. The panel included Donald Rucker, M.D., Vice President and Chief Medical Officer for **Siemens Medical Solutions USA**. Dr. Rucker is chairman of PMC’s ad hoc task force on HIT, which served as a resource for Dr. West in his research.

“As policymakers focus on improving health care quality, while lowering costs, and creating jobs to jumpstart the American economy, they need to ensure that the HIT framework facilitates the integration of genomics into health care which can simultaneously accomplish these goals,” Dr. Rucker said.

The report identified eight specific steps that would aid in the adoption of health informatics for personalized medicine, including developing “meaningful use” rules that require HIT systems to incorporate genomic information; incentivizing only HIT systems designed to aggregate data for research purposes; and revising medical privacy rules to better balance privacy with innovation.

The report is available for download at [www.personalizedmedicinecoalition.org/policy/topics/health-information-technology](http://www.personalizedmedicinecoalition.org/policy/topics/health-information-technology).

## Moffitt Cancer Center Puts Personalized Medicine Into Practice

Following is an excerpt from an acceptance speech by William (Bill) S. Dalton, Ph.D., M.D., President and Chief Executive Officer and Center Director of the Moffitt Cancer Center, for PMC's "Leadership in Personalized Medicine" award. The award is given annually at the Harvard Personalized Medicine Meeting to recognize an individual whose contributions in science, business, and/or policy have helped advance personalized medicine.

I would like to first thank Harvard Medical School and Harvard Business School, and **Partners Healthcare Center for Personalized Genetic Medicine** for establishing what is considered the premier event in personalized medicine. In particular, I would like to thank Dr. Raju Kucherlapati, a true pioneer in taking the concept of "personalized medicine" from concept to reality.

I would also like to thank the Personalized Medicine Coalition, its President Edward Abrahams, and the founder and immediate past-President Brian Munroe. I am honored and humbled to accept this award on behalf of the **H. Lee Moffitt Cancer Center** and its many partners who strive to advance cancer research and care.

Cancers are an ideal model for the discovery, translation and delivery of personalized medicine. One out of every two men and one of every three women will develop cancer in their lifetime in the United States. To improve outcomes, we must find better, more precise, approaches to preventing and treating cancers.

The Moffitt Center's approach to personalized cancer care began almost eight years ago. We call this approach "Total Cancer Care™." Its goal is to identify and meet all a patient's needs. The essence of the approach is to not only treat the cancer, but to focus on individual care, to search for solutions, not just cures. We believe this will reduce death and suffering due to cancer. In order to do so, we seek to:

- 1) Create a system to identify the needs of individual patients;
- 2) Identify markers to predict needs and risks so that interventions become preemptive;
- 3) Identify molecular signatures for patients who are unlikely to respond to standard of care;



PMC Past-President Brian Munroe presents William Dalton with the "Leadership in Personalized Medicine" award.

- 4) Utilize clinical characteristics and molecular profiling techniques to match the right patient to the right treatment at the right time and the right place; and,
- 5) Integrate new technologies in an evidence-based approach to maximize benefits and reduce costs.

We developed a large regional cancer biorepository, in parallel with a relational data warehouse and an information system containing patient clinical data and molecular data.

We soon recognized that although Moffitt had a large patient population, we would need hundreds of thousands of patients to study. Our Florida-wide network of hospitals and physicians was enthusiastic about participating in what became the Total Cancer Care™ Protocol. This IRB-approved protocol sought patient consent to collect and store clinical data, to study any excess tumor or normal tissue using molecular profiling techniques, and to recontact patients as needed.

We hope that our effort will be part of the foundation of what will someday be considered commonplace—a health care system and technologies that are organized to identify and meet every patient's needs. Ultimately, by developing evidence-based health systems we will improve quality of health care by identifying best options for patients based on their personal traits and characteristics; such is the promise of personalized medicine and personalized cancer care.

## Many Doctors Know Little About Personalized Medicine, But Are Eager to Learn, Study Finds

BY JERRY COAMEY

Molecular diagnostics are a critical driver of personalized medicine, offering the potential to improve screening, sharpen diagnosis, and optimize treatment. However, does the health care industry know what the ultimate end user—the physician—really thinks about molecular diagnostics as they relate to his or her practice? That knowledge could provide valuable insight for marketing and sales executives seeking to understand the barriers to and catalysts for adopting a particular personalized medicine product or service.

**CAHG** recently concluded a study of physicians' awareness of and attitudes toward personalized medicine. Our findings show that physicians are eager to learn more about molecular diagnostics and are willing to get that information from industry, including its sales force. At a time when the pharmaceutical, biotechnology and diagnostic industries face challenges in gaining access and adding value to this critical customer, in the area of personalized medicine, the physician's door is wide open.

### Little Knowledge, Lots of Interest

We enrolled 801 U.S. physicians from oncology (n=251), cardiology (n=250), and primary care (n=300) in a quantitative, 120 question, web-based study conducted from mid-July to mid-August 2010. The study gauged doctors' knowledge, opinions, and use of personalized medicine techniques (including genomics and molecular diagnostics) and captured an array of demographic and attitudinal data, providing insights into their adoption of these technologies.

CAHG's study corroborates earlier findings by the **American Medical Association** and **Medco** that physicians in general have a very low level of knowledge and education about personalized medicine. It found that only 8 percent of doctors are very familiar with the current issues and advances in personalized medicine, and 50 percent have received no personalized medicine education at all, in medical school or afterward.

However, lack of knowledge does not dampen physicians' interest in personalized medicine. Physicians are extremely optimistic about the potential benefit of this emerging area on their profession and practice, our study found.

Nearly nine in 10 state that personalized medicine will have "some" to "a great" influence on the medical profession in general, and eight in 10 say it will have a similar level of influence on their specific practices.

### As Physician Confidence Lags, so Does Adoption of Molecular Diagnostics

One of the most compelling findings in the study was the significant lack of confidence among physicians with regard to molecular diagnostic testing. This lack of confidence was demonstrated across an array of questions including those

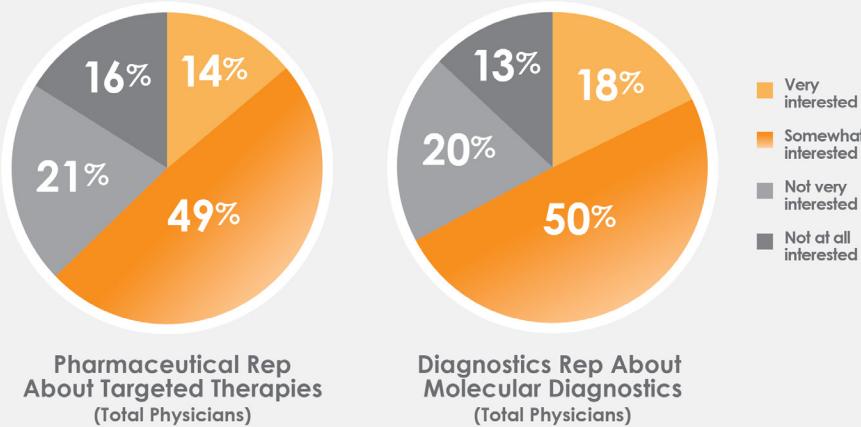
#### Physician confidence with molecular diagnostic tests

I am confident I can... (% choosing "4" or "5")	PCP	Cardiologist	Oncologist
Explain test results to my patients	46%	61% ▲ P	84% ▲ P, C
Identify appropriate patients for testing	45%	57% ▲ P	85% ▲ P, C
Understand and interpret the test results	42%	52% ▲ P	83% ▲ P, C
Choose the right test	35%	50% ▲ P	83% ▲ P, C
Choose which lab to send tests to	30%	35%	56% ▲ P, C
Determine if the test is covered by insurance	24%	30%	39% ▲ P, C
Determine the right insurance codes	23%	25%	34% ▲ P, C

▲ P = Significantly higher than Primary Care.

▲ P, C = Significantly higher than Primary Care and Cardiology.

## Interest in meeting with a sales representative



Q: How interested are you in meeting with a pharmaceutical rep to learn about targeted therapies?  
 Q: How interested are you in meeting with a diagnostics rep to learn about molecular diagnostics?

gauging which test to order and how to interpret and explain the results, to those asking about seemingly basic information such as which lab to send tests to and which insurance code to use.

For example, only a little over one third of primary care physicians and about half of cardiologists agree with the statement: "When it comes to molecular diagnostic tests, I am confident I can choose the right test."

Similarly, only 42 percent of primary care physicians and 52 percent of cardiologists said they are confident that they can understand and interpret test results.

### Oncologists More Confident

Overall, oncologists are more confident in using molecular diagnostic tests than are their cardiology and primary-care colleagues.

But even they have doubts about laboratory and insurance issues. Only 56 percent of oncologists are confident they can choose which lab should process test results, while only 34 percent are

confident they can determine the right insurance codes.

Given the critical role these tests will play in the adoption of personalized medicine, boosting physicians' confidence about their ability to use and understand molecular diagnostic tests is critical.

### Personalized Interest = Opportunity for Education

The study also revealed that physicians are strongly interested in learning more about molecular diagnostics and receptive to education by the medical industry.

An overwhelming majority of physicians—nine in 10—said they wanted to learn more about personalized medicine as it relates to their practice. Nearly seven in 10 said they would be willing to meet with a diagnostics representative to learn about molecular diagnostics, and six in 10 said they would meet with a pharmaceutical representative to learn about targeted therapies. Physicians are optimistic about the future influence and potential benefit of personalized medicine on their profession and their practices.

In fact, four out of every five physicians surveyed said they would be interested in taking a molecular diagnostic test themselves. When asked which options for molecular diagnostic tests they would be most interested in, 42 percent indicated interest in testing for a specific health condition or issue, and 36 percent indicated interest in testing for all known health issues at once. Only 22 percent stated they would never have such a test.

As more molecular diagnostic platforms and assays move from research to development and approval, especially as they move closer to point-of-care application, physicians will be confronted with a potentially dizzying array of options, choices, and information that they may be ill-prepared to handle.

Overall, physicians' optimistic attitude and still-developing knowledge of personalized medicine underscore the need and opportunity for the medical community—including industry—to provide educational programs and informational materials to prepare physicians for the influx of new personalized-medicine products. Such initiatives can only help to further accelerate adoption of personalized medicine from promise into practice.

*CAHG is a healthcare communications company; the views expressed in this article are those of the author and do not necessarily represent the opinions of the Personalized Medicine Coalition. For more information about this study, see Jerry Coamey's white paper at [http://www.cahg.com/news/pdf/CAHG\\_Landmark\\_Physician\\_Study.pdf](http://www.cahg.com/news/pdf/CAHG_Landmark_Physician_Study.pdf), or contact him at [jerry.coamey@cahg.com](mailto:jerry.coamey@cahg.com).*

# Incentives Key to PMC Plans for 2011

*continued from page 1*

Adriana devoted the last days of her life to conveying an essential message: patients like her deserve better. "A targeted cancer drug kept me alive for nine years," she wrote.

"Congress must ensure that future patients get the same chance to live." She asks why there are not more personalized medicines on the market like Herceptin®, which

she credits with giving her nine extra years, and points to the business model challenges of developing products for smaller subpopulations. She calls especially for incentives similar to those outlined in the Orphan Drug Act—longer market exclusivity and fast-track regulatory review at the Food and Drug Administration (FDA)—to overcome what she says is the pharmaceutical industry's reluctance to invest in targeted therapeutics.

Although the pharmaceutical industry may have been slow to embrace personalized medicine, many signs point to its increased investment

in the new paradigm, despite the problem Adriana identifies. Drugs like Herceptin®, as Adriana writes, can indeed be "blockbusters." According to the Tufts Center for the Study of Drug

Development's survey of 25 pharmaceutical and biotechnology companies, published last November, between 12 and 50 percent of medicines in pharmaceutical pipelines

are targeted therapeutics, though as compounds move closer to market, those tied to a biomarker strategy decline to 30 percent and only 10 percent have companion diagnostic in co-development.

The pharmaceutical industry's growing commitment to personalized medicine does not make Adriana's message less compelling. Incentives to encourage more investment in personalized medicine products can hasten progress for patients, perhaps even more powerfully than any other measure. Not insignificantly, it will also help the industry increase its productivity, which has declined in

recent years despite dramatically higher investments in research and development, leading not only to fewer, new life-saving drugs but to fewer jobs as well.

Moreover, unless FDA addresses the current confused environment that governs the regulation of personalized medicine products, pharmaceutical companies will be less likely to launch drugs with companion diagnostics. Unless we develop the evidence and convince public and private payers that personalized medicine products are worth paying for, it will be that much harder to justify investment in sophisticated diagnostics. And unless we also persuade providers to adopt new treatments and personalized medicine approaches, progress will be slower than we—and patients like Adriana—wish.

As Adriana argues, we must incentivize industry, using every governmental lever at our command, to encourage the development of more drugs like Herceptin®, Gleevec®, and other medicines that offer a better future for patients. PMC plans to honor her dying wish, and to make Adriana's plea central to our plans this year.

Brain problems are a big part  
of healthcare costs. *Integrative  
Neuroscience and Personalized Medicine*  
reflects the solutions proposed by  
key US scientists, clinicians, and  
healthcare stakeholders for global  
Personalized Medicine.

2011 | 360 pages | 9780195393804 | \$89.95/\$67.45

**OXFORD**  
UNIVERSITY PRESS

4 Easy Ways to Order • Promo Code: 29416

•Phone: 800.451.7556 •Fax: 919.677.1303 •Web: [www.oup.com/us](http://www.oup.com/us)

•Mail: Oxford University Press, Order Dept., 2001 Evans Road, Cary, NC 27513



# Personalized Medicine Coalition Announces New Board Appointments

The Personalized Medicine Coalition has elected two leaders in personalized medicine to its board: William (Bill) S. Dalton, Ph.D., M.D., President, Chief Executive Officer and Center Director of the **H. Lee Moffitt Cancer Center**, and Jared N. Schwartz, M.D., Ph.D., Chief Medical Officer, **Aperio**.

The new board members, representing clinical practice and digital pathology, expand the diversity of experience and interests on PMC's Board of Directors.

A nationally renowned cancer researcher, physician and health policy expert, Dr. Dalton has dedicated his career to the study and development of the most effective approaches to cancer research and care. For his leadership in the development of personalized cancer care and patient-centered outcomes research, Dr. Dalton was recognized as the 2010 recipient of the Personalized Medicine Coalition's Leadership in Personalized Medicine Award. Moffitt is a designated Comprehensive Cancer Center of the National Cancer Institute.

"Studies of cancers have been the training ground for the discovery, translation and delivery of personalized medicine," Dr. Dalton said. "In order to accelerate the process, we must bring together primary stakeholders including researchers, clinicians, industry, policymakers, and patients themselves to organize the framework and environment to promote personalized medicine. I look forward to working with PMC to promote that collaboration."

Jared Schwartz brings 30 years of pathology expertise to PMC. Before joining Aperio, he recently served as President of the **College of American Pathologists**, and last year was named 2010 Pathologist of the Year, the organization's highest honor. Dr. Schwartz also was Director of Pathology and Laboratory Medicine at Presbyterian Healthcare in Charlotte, North Carolina. Board certified in anatomic and clinical pathology with subspecialty boards in medical microbiology and cytopathology, Dr. Schwartz is a graduate of **Duke University** Medical School, where he completed his residency and fellowship training and served as chief resident. In addition to his responsibilities at Aperio, Dr. Schwartz is also a Consulting Professor in the **Stanford University** Pathology Department.

"As President of the College of American Pathologists, I worked with our leadership to help pathologists prepare for



William S. Dalton, Ph.D., M.D.



Jared N. Schwartz, M.D., Ph.D.

the critical role they would play in the era of personalized medicine," Dr. Schwartz said. "In addition, we stressed the positive impact new technologies would have on pathologists' abilities to provide higher quality and more precise care to patients.

"Embracing technologies such as digital pathology and molecular diagnostics will directly enhance our tools to deliver high-quality personalized medicine. I look forward to working with the PMC as it seeks to broaden the understanding and awareness of personalized medicine within the health care community and among health care policy professionals, and most importantly to advocate that patients have access to truly personal care."

Dr. Dalton is Board Chairman of M2Gen, a national biotechnology subsidiary of Moffitt Cancer Center. He is President-Elect of the Association of American Cancer Institutes and Chair of the Science Policy & Legislative Affairs Committee of the **American Association for Cancer Research**. He also serves on the Institute of Medicine's National Cancer Policy Forum and was a member of the National Cancer Institute (NCI) Board of Scientific Advisors, as well as other scientific advisory boards at cancer centers and research foundations.

Dr. Schwartz was appointed to the Clinical Laboratory Improvement Advisory Committee by HHS, and was a co-chair and author of the ASCO/CAP Guidelines on HER2, which was published in the January 2007 editions of the *Journal of Clinical Oncology* and *Archives of Pathology and Laboratory Medicine*.

# PMC IN THE PRESS

**Politico** reported in March on a two-day hearing by an advisory panel of the Food and Drug Administration. The hearing, which looked at how to regulate consumer genetic testing companies, pitted PMC members that offer consumers genetic tests against the **American Medical Association** (AMA). AMA urged the panel to require tests be conducted only under the guidance of health care providers. PMC Public Policy Director Amy Miller told *Politico* she questioned FDA's scrutiny of the issue given its other priorities. "This is such a small subset of testing," she said. "It's not the best use of time."

The **Jackson Laboratory**, based in Bar Harbor, Maine, will expand its operations with a new facility to focus on personalized medicine research in Sarasota County, Florida, the **Sarasota Herald-Tribune** reported in February. The article quoted PMC President Edward Abrahams who described the research institution as "extremely prestigious" and "world-renowned."

A pair of stories in **Inside Health Policy** and **The Pink Sheet** at the end of January noted PMC Public Policy Director Amy Miller's dissatisfaction that a private-sector expert in personalized medicine or genomics was not appointed to the Patient Centered Outcomes Research Institute's Methodology Committee. The stories stemmed from her post on *The Age of Personalized Medicine Blog*. "This will make it all the more important for leaders in the personalized medicine field to continue to advocate for alignment of personalized medicine and comparative effectiveness research in the development of research methods and study designs," she wrote.

In a January analysis of the landscape for personalized medicine in 2011, **GenomeWeb** quoted PMC Public Policy Director Amy Miller about the prospects for legislation to overcome barriers to personalized medicine in the newly-elected Congress. Although a divided Congress is a difficult legislative environment for health care advocacy, she expresses optimism that "personalized medicine is not a partisan issue; members of all parties want higher quality health care."

Richard Katz, M.D. and Timothy McCaffrey, Ph.D., professors of medicine at **The George Washington University**, and Jack Lewin, M.D., Chief Executive Officer

of the American College of Cardiology, in January discussed new personalized cardiovascular medicine technologies and the clinical adoption of new approaches to cardiovascular treatment on **BioCentury This Week**, a television program. The program kicked off PMC's *New Frontiers in Personalized Medicine: Cardiovascular Research and Clinical Care* conference, at which all three men spoke.

Survey results released at PMC's cardiology conference by the American College of Cardiology showed that clinical adoption of pharmacogenomic testing lags behind optimism in the medical community about the potential to reduce adverse effects and improve patient outcomes through personalized medicine, **The RPM Report** said in January. The article also quoted conference speaker Russell Teagarden, Vice President of Scientific and Academic Affairs at **Medco Health Solutions, Inc.**, who noted his company's success in boosting testing rates through additional contact with physicians.



**The Baltimore Sun** reported in January that The Johns Hopkins University received a \$30 million gift from John C. Malone, chairman of Liberty Media Corp., to create a center for personalized medicine. "[O]ne-size-fits-all medicine isn't going to work in the future," PMC President Edward Abrahams told the paper. "The only way we'll get results is through greater understanding of individual variation."

The Personalized Medicine Coalition released a report that highlights the outdated reimbursement framework for personalized medicine diagnostic tests, **CQ HealthBeat** and **The Gray Sheet** reported in December. Quoting the report, written by **Boston Healthcare Associates'** David Parker, *CQ HealthBeat* noted that "inappropriate reimbursement inevitably tends to inhibit access" to new tests.

As health reform implementation continues, the Personalized Medicine Coalition nominated a slate of experts from industry and academe for the Patient Centered Outcomes Research Institute Methodology Committee, reported **FDA Week**, **The Pink Sheet** and **Pharmacogenomics Reporter** in November. The articles noted the nominees' experience and also reported the health reform law's requirement that the Committee consider genomics when designing comparative-effectiveness research standards.