AFTER MONTHS OF TESTS, treatments, and painful side effects following her late-stage cancer diagnosis, Stephanie Haney, mother of two, feared she would not live much longer. Remarkably, months later, Stephanie’s tumor was no longer growing and she was able to return to work.

Her recovery was the result of innovations in tumor profiling, the process of detecting and analyzing molecular alterations in an individual’s cancer genome, and the development of new drugs that target cancer at the molecular level. Genetic testing of Stephanie’s tumor revealed that because her cancer was abnormal for the $ALK$ gene, a targeted therapy called crizotinib could be used to inhibit its growth.

Though other targeted therapies like the one that saved Stephanie’s life are available, her story is the exception rather than the rule. Only 25 percent of oncologists who responded to a survey at the Dana Farber Cancer Institute indicated that they plan to use genomic testing on most of their patients. A lack of knowledge may be one reason why molecular treatments are overlooked.

continued on page 8
PMC Continues to Advance Its 2014 Agenda

BY EDWARD ABRAHAMS, PMC PRESIDENT

This year PMC celebrates its tenth anniversary focused on three interrelated themes: education, reimbursement, and sustaining innovation to accomplish our mission—

**Education**
Recognizing that most health care providers, never mind patients, have not been introduced to the principles of personalized medicine, under the direction of PMC’s new chair, William Dalton, Ph.D., M.D., PMC has redoubled its emphasis on education with new plans to extend our outreach. The fourth edition of the Coalition’s signature document, *The Case for Personalized Medicine*, was released at the PMC/BIO Forum on Diagnostics and Personalized Medicine in San Diego on June 25 as the first step in an effort to focus more on education.

PMC also plans to become a focal point for the integration of personalized medicine into clinical practice. With the assistance of our members, the Coalition will strive to determine the best practices for facilitating the integration of personalized medicine into health care.

Our initiative comes on the heels of the publication of a new article in the *Journal of Clinical Oncology* that documents the widespread lack of awareness, even among oncologists, regarding targeted therapeutics. That unfamiliarity negatively impacts patient care. Physicians who lack confidence in their understanding of multiplex tumor genomic testing are much less likely to use them to help guide cancer care.

Noting also that the limited education of health care professionals in personalized medicine has slowed its adoption, PMC plans to collect and curate materials for health care providers and policymakers. These materials will be hosted on our website and be made available for a wide audience, creating a unique product for the field. In addition, under the direction of leadership provided by PMC, student chapters have been encouraged to organize to consider developments in personalized medicine.

**Reimbursement**
Knowing also that personalized medicine, if not medical progress in general, depends on our willingness and ability to pay for new diagnostic and therapeutic products, this year PMC has focused its advocacy efforts on coverage and payment issues. We were pleased that Patrick Conway, M.D., Chief Medical Officer at the Centers for Medicare and Medicaid Services, underlined his belief at PMC’s Tenth Annual State of Personalized Medicine Address that the government’s coverage and payment policies must also, in addition to cost, consider their impact on access and innovation, something that has not always been obvious given the downward pressure on diagnostics the industry has recently experienced. For excerpts from Dr. Conway’s address, see page 14, and for a more in depth discussion of the Coalition’s initiative on reimbursement, see Amy Miller’s policy brief on
page 6, which includes discussions of PMC’s new white paper, *The Future of Coverage and Payment for Personalized Medicine Diagnostics*, and our additional forthcoming analysis of how alternative payment models can impact the future of personalized medicine.

**Sustaining Innovation**
Closely connected to PMC’s efforts to shape policy regarding coverage and reimbursement is the Coalition’s focus on sustaining innovation in health care. PMC has two other major efforts in the works.

First, on October 9, along with our partners the American Association for Cancer Research and Feinstein Kean Healthcare, PMC will convene a major conference in Washington, D.C. that explores the public policies which support patient-centered cancer care along with a better understanding of the important and widely misunderstood issues of cost, value, and medical progress in an environment characterized by increasing price resistance to new drugs, no matter how efficacious. The conference will ask—and seek to answer—two key questions: (1) What policies do we need to support patient-centered cancer care and research and (2) How can we create incentives for innovation that encourage both?

And, second, to better understand the future of personalized medicine and to answer those skeptics who contend that the industry is under-investing in meeting unmet patient needs, PMC will commission an updated analysis of the pipeline for personalized medicine products and their market prospects. The analysis will involve interviewing senior leaders in both the pharmaceutical and diagnostic industries regarding the challenges that they face to develop and market companion diagnostics.

**Conclusion**
We understand that this is an ambitious program, but are confident that with the support of our members, our goals are obtainable.
Incentivizing Innovation
PMC submitted comments in response to the House Energy & Commerce Committee’s white paper, “21st Century Cures: A Call to Action.” These comments highlighted PMC’s educational documents and policy positions, including:

- Personalized Medicine Regulation: Pathways for Oversight of Diagnostics
- The Future of Coverage and Payment for Personalized Medicine Diagnostics
- Support for policies that incentivize personalized medicine through transparent and predictable policies that encourage growth and investment in this area

Facilitating Dialogue
PMC’s Science and Policy Committees met June 3 to discuss best practices for the integration of personalized medicine into health care, the reimbursement and innovation initiatives, and legislative updates.

PMC welcomed guest speaker Gurvaneet Randhawa, M.D., M.P.H., Medical Officer & Senior Adviser on Clinical Genomics & Personalized Medicine at the Agency for Healthcare Research and Quality (AHRQ), who discussed AHRQ’s role in the evaluation of personalized medicine products and services, noting the unresolved issue of evidence development for different kinds of health care products.

Addressing Reimbursement
As part of the ongoing reimbursement initiative, PMC submitted two letters to the Centers for Medicare & Medicaid Services (CMS).

The first responds to the agency’s Request for Information (RFI) on specialty practitioner payment models. After explaining the importance of sustaining growth in personalized medicine and the impact that payment models might have on the development of personalized medicine, PMC suggested that CMS:

- Proceed only after a thorough evaluation of new models
- Avoid models that hold health care in a “one-size-fits-all” paradigm
- Account for the long-term benefits of personalized medicine

The second letter addresses CMS’ gapfill payment amounts. PMC outlined concerns about the unintended consequences of the proposed gapfill payments on the future of personalized medicine, including the following:

- The halting of drug-diagnostic company collaborations which, in turn, will impede the development of targeted medicines
- The discouragement of investments in the life sciences
- National job loss in the science and technology sectors

In an ongoing effort to advocate for policies that encourage the development of personalized medicine, PMC has engaged with leaders in Congress and at CMS this year.
The Personalized Medicine Coalition invites you to attend a networking cocktail reception to kick off the Tenth Annual Personalized Medicine Conference at the Hotel Commonwealth.

**Tuesday, November 11, 2014 • 5:30 – 8:30 p.m.**
Hotel Commonwealth • 500 Commonwealth Ave, Boston, MA

Registration is free for PMC members, press and government. Non-members are welcome to attend for $100.

To RSVP, please visit:
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Event sponsored by
Unlocking Personalized Medicine With Coverage & Payment Policies

BY AMY MILLER, PMC EXECUTIVE VICE PRESIDENT

By controlling access to diagnostics and targeted therapies, coverage and payment policies serve as either a lock or a key for personalized medicine.

In recognition of how important these policies are, PMC has developed a multi-faceted initiative on reimbursement issues. As part of this initiative, we invited Patrick Conway, M.D., Centers for Medicare and Medicaid Services (CMS) Chief Medical Officer, to give our annual state of personalized medicine address. During his address at the National Press Club, he stated that policymakers do not intend to disincentivize innovations through payment policy; rather, he said, it is an unintended consequence that can be avoided with diligence, awareness, and an orchestrated effort to educate them. Therein lies the purpose and focus of our reimbursement initiative—to educate policymakers.

PMC’s message to policymakers, expressed in letters to CMS and in thought leadership papers on reimbursement, has been clear and emphatic.

We advocate for policies that:
- Avoid holding health care in a “one-size-fits-all” paradigm
- Account for the long-term benefits of personalized medicine
- Are developed with transparency and stakeholder participation
- Are put into place only after a thorough evaluation of their long-term implications
- Include mechanisms to support the adoption of advances in personalized medicine

To educate policymakers and the broader personalized medicine community on the current and future state of reimbursement issues, PMC has just released *The Future of Coverage and Payment for Personalized Medicine Diagnostics*. With input from our members, the white paper was drafted by Bruce Quinn, M.D., of Foley Hoag, a leading authority in the field.

The paper provides an overview of how diagnostics have evolved over time and how policies to pay for them have struggled to keep up. It also outlines the challenges personalized medicine will face in the coming years in three major policy areas.

These include:
- **Imminent Federal Pricing of Highly Innovative Molecular Tests**: Between 2012 and 2014, many changes were made regarding how genomic tests were coded and priced. As an unintended consequence, many genomic tests were not paid for during the first quarter of 2013. In the face of even larger policy decisions in 2014 and 2015, it is crucial that we insist that reimbursement levels ensure access to high-quality diagnostics and encourage the development of additional innovative tests that require substantial risk-based research.
- **Inconsistent Standards and Paradigms for Evaluating Diagnostic, Prognostic, and Predictive Genomic Tests**: Although most agree that genomic tests create a benefit by having an...
impact both on patient management and the delivery of treatments, many are still concerned that processes for defining “clinical utility” are neither clear nor predictable. The community should outline reasonable and reliable standards for these evaluation processes.

- **Lack of Incentives for Genomic Medicine:** There are areas where genomic medicine could impact public health, but the traditional reimbursement system fails to provide enough incentive for its development. Creative incentives such as tax credits and/or preferential payment models are greatly needed.

  We have an historic opportunity. CMS and private payers are considering new payment models that can improve efficiencies and reduce costs when paying for health care. Since these alternative payment models (APMs) are novel, it is possible for us to shape them in a way that supports innovation.

  Imagine a health care payment system that “pays for value,” with personalized approaches to care, targeted pharmaceuticals, and the tests designed to select, dose, or avoid them covered by payers at a price point that supports innovation. In a forthcoming white paper on APMs, we will make that argument and outline what such a model might look like.

  The U.S. House of Representatives Energy and Commerce Committee has launched a 21st Century Cures Initiative, which represents a significant opportunity to suggest policies that could advance innovations throughout the lifecycle from discovery to development and delivery. This bipartisan effort has received a lot of attention. With a little creativity and some effort to forge consensus among our members, we will be able to develop and advocate for policies that reward personalized approaches to care, rather than inhibit them.

  Our call to action is to monitor, evaluate, and contribute to the debate by suggesting policy solutions that will ensure that personalized medicine is integrated into the development of payment policies in the years ahead. We have an opportunity to define how that is done. The personalized medicine community has envisioned improvements to health care. It has invested in the research to develop them and seen them through regulatory hurdles. That creativity must now be focused on outlining payment policies that support personalized medicine and reward innovations in health care.

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continued from page 1

Boosting Confidence With Knowledge
Many physicians, including oncologists, report a lack of confidence in their knowledge of genomics and in their ability to explain it to patients. The confidence gap is even greater among oncologists in community practice, where the majority of patients receive care. Edmund Tai, M.D., a community oncologist with Palo Alto Medical Foundation, a branch of Sutter Health in Mountain View, CA, said his practice only does tumor testing for some patients who have failed standard treatments. For Dr. Tai and his colleagues, one of the biggest barriers to employing genomic testing is interpreting the results.

Even with a recent training in intensive genomics, Dr. Tai says the volume of information he receives from the tests can be daunting. “The results can show a tumor has five different mutations,” he explained. “All could be responsible for why the cancer is not responding to treatment. Which one do you deal with?”

It’s a question oncologists are increasingly being asked to answer, as patients read news stories about genomic testing and personalized cancer treatment and ask how it might benefit them.

Partners Can Help Guide Decisions
Clearly, a concerted effort to educate clinical oncologists about the benefits of molecular diagnostics would help boost their confidence in the use of the technology. However, they do not have to become experts in cancer genomics.

Deborah Morosini, M.D., a pathologist and Vice President of Clinical Development at Foundation Medicine, noted that oncologists who know the correct use of a test and which patient should be tested can confer with an expert partner to interpret the results and decide on next steps.

Foundation Medicine’s genome sequencing product FoundationOne® identifies gene mutations in a patient’s tumor sample and provides the oncologist with information

“We don’t have anything for many of our patients. I deal with a lot of death and dying. If there is hope that something can change that, we should pursue it.”

— Edmund Tai, M.D.

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Save the Date
Thursday, October 9, 2014
Turning the Tide Against Cancer National Conference

Knight Conference Center at the Newseum
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Join the cancer community and policymakers to advance patient-centered solutions that support innovation and high-value cancer care in the face of rising costs.

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regarding relevant targeted therapies and clinical trials. “Once you’ve found a genetic alteration in a patient’s tumor, you can use an off-label therapy or clinical trial that matches the alteration,” Dr. Morosini said. “You’re looking at a genomically based rationale for off-label use, which is usually used haphazardly.”

Cancer genomic testing and diagnostic services are also offered by other companies, including the KEW Group, Caris Life Sciences, and N-of-One. Their tests open doors for potential new treatments. According to Chris Cournoyer, CEO of N-of-One, her company is “committed to providing scalable, cost-effective genomic clinical decision support that delivers valuable analysis and interpretation … to support oncologists in making molecular informed treatment decisions for their patients.” In May, N-of-One announced an agreement with the Mayo Clinic to do just that.

The next-generation sequencing technology used by N-of-One and hundreds of others has resulted in an explosion of genomic information relevant to cancer. Demonstrating clinical validity and utility for these comprehensive tests, however, remains time consuming and expensive. It requires a creative approach outside of the traditional clinical trial structure, which can be slow and cumbersome.

Body of Evidence from Master Protocol

It’s difficult for oncologists to know which genomic test is better than another, Dr. Tai said. Until now, there were no data proving that next-generation sequencing ultimately increases patient survival, contributing to the hit-or-miss reimbursement practices of third-party payers. “There are a lot of tests being done, but we don’t know how well they’re being done or their impact on the care of the patients,” said Michael Kolodziej, M.D., Aetna’s National Director for Oncology Affairs and a PMC board member. “We have issues with the analytic validity and the clinical utility. And that’s holding us up right now.”

Generating data to validate the clinical utility of cancer genomic tests and to test investigational targeted therapies are among the goals of the Lung Cancer Master Protocol, designed by a coalition of cancer research organizations under the leadership of Friends of Cancer Research. The multi-drug, multi-center Phase II/III registration trial will use FoundationOne® to stratify patients into appropriate target-specific arms to help determine the value of sequencing tumors in advance of prescribing therapies.

About 6,000 patients with squamous cell lung cancer will be screened for the trial, which will begin with five investigative compounds, all of which have shown biologic activity against a measurable target. Combinations of agents can be used, as appropriate, with the goal of developing each molecule with a companion diagnostic. “That’s the kind of evidence that payers need to see,” Dr. Kolodziej said.

More Options for Cancer Patients

Three years ago, there wasn’t much conversation about molecular diagnostics among Dr. Tai and his colleagues. Now, the Palo Alto Medical Foundation is increasingly focused on this area of medicine.

An oncologist for 27 years, Dr. Tai said his frustration with treatments that are not effective for some patients motivated him to pursue genomic testing and targeted therapies. “We don’t have anything for many of our patients,” he said. “I deal with a lot of death and dying. If there is hope that something can change that, we should pursue it.”
Don’t miss out on the conversation.

At Genome magazine, we’re exploring the world of personalized medicine and the genomic revolution that makes it possible.

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AS MY COLLEAGUES AND I pointed out in a white paper published by Xifin (www.xifin.com/resources) last year, “Genetic testing, molecular diagnostics, genomic testing, and personalized medicine are fundamentally different from and will change traditional diagnostics and medicine. The difference ... is comparable to that between devices and 'smart' devices; a room knows when someone has entered and turns on the lights, a car knows when it is skidding and applies the anti-locking break system. Very specific technology-provided information ... alters outcomes in a manner completely impossible without the added information. Similarly, very specific information provided by molecular diagnostics on selected patients can alter the course of medical treatment in a manner completely impossible without the added information.”

This is the promise of personalized medicine, which allows for the possibility of rapid, precise, and individualized application of various therapies, including drugs, surgery, radiation, devices, watchful waiting, or other clinical strategies offered to patients. When its speed and precision are coupled with knowledge and tools for appropriate application and compliance/adherence, personalized medicine can optimize outcomes, mitigate costs, and eliminate waste in health care, which is now estimated to approach $350 billion a year in the United States, according to the Institute of Medicine's Best Care at Lower Cost (2012). Data may be the key to addressing wasteful spending, as the decreasing costs of applying the revolutionary measurement methods associated with personalized medicine while generating ever more valuable data (much never previously considered or imagined) continue to deliver dramatic increases in productivity.

But unfortunately, our health care system must overcome profound challenges if it is to fully realize the benefits of personalized medicine. Despite a moderating rate of inflation, the monetary growth of the health system is still faster than that of the overall economy, and may soon represent an alarmingly large part of the nation's GDP.

Outside the United States, most health care systems are so-called “single-payer,” with governments asserting centralized controls to increase participation, reduce cost growth, standardize quality, and ration care. In this uncertain economic environment, which is
compounded in the United States by the Accountable Care Act, the costs of research associated with personalized medicine, not to mention the need to develop sufficient clinical data in order to obtain payment, have increased the cost of developing personalized medicine diagnostics.

Estimates suggest that targeted drugs can cost developers as much as $1.2 billion before they reach the market, and hundreds of millions have been required to successfully launch some sophisticated diagnostic products, which, unlike drugs, do not have a history of value-based payment. Those development costs put early stage investment in diagnostics at risk.

A new process that reduces the cost of generating the required data necessary to secure coverage and payment is therefore critical. It would spur increased investment in personalized medicine diagnostics and speed commercialization of personalized medicine products, allowing society to address unmet patient needs, lower overall costs, and eliminate waste.

My colleagues at Xifin and I contend that we need a new system to promote investment in diagnostics. It would focus on three principles:

1. **Risk Sharing**
   The proposed system would provide value-graded payment after analytic and clinical validation, which could be recouped or reduced if the promised clinical utility is not realized.

To not act promptly jeopardizes the future and perpetuates the ineffective diagnosis, monitoring, and treatment of patients that is now the norm, putting at risk a new generation of diagnostic products that are both “smart” and persuasive.

With appropriate tools to measure successful outcomes, in this system of shared risk each party would benefit from cheaper and more rapid clinical utility determinations by cooperating and instituting technology-based knowledge systems that optimize application.

2. **Data Exchange**
   The system would also feature universal clinical data collection and aggregation, unbiased repository creation, and analytic software that can deliver real-time data to inform laboratory reports and clinical decisions. Repositories would capture clinical outcomes, surrogate endpoints (if used), specific biomarkers, and methods. Incentives to emphasize more precise diagnosis, prognosis, monitoring, or prediction of action response as outputs of these data would be required.

3. **Pay for Value Not Service**
   Finally, test developer estimates of value with real-world data that invites early coverage and reimbursement would be of paramount importance. The system would pay more for diagnostics that are more precise, impact treatment, have demonstrated utility, and meet the needs of our health care system for better patient outcomes and lower overall cost.

Others have proposed less dramatic alternatives to our principles and suggestions for a new reimbursement system. In selected cases, for example, federal payers have offered Coverage with Evidence Determination (CED) as a novel pathway. We are skeptical, however, that in the rapidly evolving world of personalized medicine, CED can provide a general solution that both speeds utility determinations and spurs innovation.

To not act promptly jeopardizes the future and perpetuates the ineffective diagnosis, monitoring, and treatment of patients that is now the norm, putting at risk a new generation of diagnostic products that are both “smart” and persuasive.

*Editor’s Note: The opinions expressed here are the author’s alone and neither reflect those of ThermoFisher, where Dr. Billings is the Chief Medical Officer (consulting), or of the Personalized Medicine Coalition. He wishes to thank his colleagues Richard Ding as well as Lale White, Rina Wolf, and David Lorber at Xifin for their input and energy in convening and working on the white paper that serves as the basis of this opinion piece.*
PATRICK CONWAY, M.D., DEPUTY Administrator for Innovation and Quality and Chief Medical Officer, Centers for Medicare & Medicaid Services (CMS), delivered the keynote address at the Tenth Annual State of Personalized Medicine Luncheon hosted by the Personalized Medicine Coalition (PMC) at the National Press Club in Washington, DC.

Attended by more than 200 innovators, patients, scientists, and government officials devoted to the understanding and improvement of health care, Dr. Conway outlined his perspective on the state of personalized medicine and where it is headed.

“Innovation is happening broadly across the country. The promise of personalized medicine and innovation is amazing, and we’re already seeing dividends,” Dr. Conway stated in his address.

Testing new models of care is critical, he said, and we have to tailor interventions to individual patients with an evidence-based approach to improve outcomes. This involves shared decision-making with patients based on substantial data and estimates from diagnostics, for example. According to Dr. Conway, CMS does not take cost into account when making coverage decisions.

“We are looking at patient outcomes; so we have to cover technology that is reasonable and necessary—and then pay for it appropriately,” he said.

Dr. Conway discussed focusing on better health outcomes for our nation and removing the barriers to personalized medicine—namely, covering treatment innovations. He explained one of the government’s core functions should be removing regulatory or other obstacles that limit innovation, while also making catalytic investments to drive these advancements.

Dr. Conway referenced a paper he wrote published in the New England Journal of Medicine, discussing a lifelong health system that he thinks is applicable to personalized medicine. If a goal of the health system is to have better outcomes and we know that health trajectories are modifiable, we can control risks over time. He noted that there is good evidence on the importance of incorporating predictive tools as they relate to health risks in order to modify risky behaviors over time.

Dr. Conway concluded his remarks by noting we have a history of innovation in this country, but we need to set up a payment system that values and pays for it appropriately.

“We are truly in an era now that is unleashing the power of genetics and other issues where we will be able to tailor therapies much more individually to patients, and that will actually get better health outcomes at a lower cost,” Dr. Conway said. “It’s good for our health system, and I think we will need to collectively work together to achieve that vision.”
BAPEMED PERSONALIZED MEDICINE CONFERENCE

BAPEMED Launches With First Bulgarian Conference on Personalized Medicine

The event took place at the Aula of Tokuda Hospital in Sofia, Bulgaria.

TO CELEBRATE THE LAUNCH of the Bulgarian Association for Personalized Medicine (BAPEMED), the first Bulgarian Conference on Personalized Medicine featured speakers from around the world, including Bulgarian Vice Minister of Health Chavdar Slavov, European Alliance for Personalized Medicine (EUAPM) Executive Director Denis Horgan, and PMC President Edward Abrahams. The event took place at the Aula of Tokuda Hospital in Sofia, Bulgaria, and was sponsored by BAPEMED.

In his keynote address to the international audience, Abrahams provided an overview of how personalized medicine is changing health care. He discussed the different definitions of personalized medicine, outlined its advantages for patients and the health care system, and noted its impact on research & development of pharmaceuticals and diagnostics. He predicted that personalized medicine would become integral to future health care systems across the globe, and would reward the countries that invested in it.

[Abrahams] predicted that personalized medicine would become integral to future health care systems across the globe, and reward the countries that invested in it.

Slavov, Vice Minister of Health in Bulgaria, agreed, declaring that the concept and principles of personalized medicine will be included in Bulgaria’s National Health Strategy until 2020.
ON JUNE 25, PMC RELEASED the fourth edition of its signature document, The Case for Personalized Medicine. If the growth in the number of products on the market is any indication, this publication is making an increasingly compelling argument for personalized medicine. 

Debuted at the Personalized Medicine & Diagnostics Forum, part of the 2014 Biotechnology Industry Organization (BIO) Convention in San Diego, The Case highlights the growing number of available personalized medicine drugs, treatments, and diagnostics. There are now 113 of these products on the market, compared to only 13 in 2006.

“With this progress comes a greater responsibility to move personalized medicine forward,” said Edward Abrahams, PMC President. “In a time of unprecedented scientific breakthroughs and technological advancements personalized health care has the capacity to detect the onset of disease at its earliest stages, pre-empt the progression of disease, and, at the same time, increase the efficiency of the health care system by improving quality, accessibility, and affordability.”

The Case discusses how personalized medicine can shift the emphasis in medicine from reaction to prevention, direct the selection of optimal therapy, help avoid adverse drug reactions, increase patient adherence to treatment, improve quality of life, reveal additional or alternative uses for medicines and drug candidates, and help control health care costs.

A full PDF version of the document and an accompanying one-page synopsis of the content, Personalized Medicine by the Numbers, are available on the PMC website at www.personalizedmedicinecoalition.org.

The number of personalized medicine diagnostics and therapeutics has risen steadily since the release of the first edition of The Case for Personalized Medicine, with the more than 113 products available today representing a profound increase since 2006.
PMC NEWS

PMC Announces New Board Member

The Personalized Medicine Coalition (PMC) announced the appointment of Jay G. Wohlgemuth, M.D., Senior Vice President, Medical, Science and Innovation, Quest Diagnostics, to the Coalition’s board of directors.

“We are pleased to welcome Dr. Wohlgemuth to PMC’s board of directors,” said Edward Abrahams, Ph.D., President, PMC. “With his valuable knowledge and experience as a scientist and as a director of innovation processes, he is well-equipped to advise the Coalition on how best to advance personalized medicine.”

In his role with Quest Diagnostics, Dr. Wohlgemuth leads all new test development efforts and is responsible for all science and innovation throughout the company. He also is responsible for Medical Affairs and has a functional reporting responsibility for Medical Quality.

“PMC educates policy makers and the general public about how personalized and precision medicine can substantially improve the quality and cost effectiveness of health care,” Wohlgemuth said. “This work is vital to ensuring molecular diagnostics are properly valued financially and develop within a supportive regulatory environment. I am honored to be elected to PMC’s board.”

Dr. Wohlgemuth has many years of experience in diagnostics and research and development. Prior to joining Quest Diagnostics in 2009, he was Director, Clinical Diagnostics, ITGR (Immunology, Tissue Growth and Repair) and Global Development Team Leader for Ocrulizumab for Genentech. He also served as Vice President, Research and Development for VIA Pharmaceuticals and as Chief Medical Officer for the molecular diagnostics company CareDx (formally XDx), a company he co-founded.

For his work at XDx he was awarded Technology Pioneer 2005 at the World Economic Forum in Davos.

PMC Welcomes Christopher Wells

Hired to enhance membership outreach and communications, Chris expands PMC’s capacity to serve its members. He has a master’s degree in public administration from Binghamton University and a bachelor’s degree in journalism from the State University of New York at Brockport. The winner of The Fender Music Foundation Leadership Award and Binghamton University’s Alpha Student Award for Overall Excellence, Chris adds depth to PMC’s staff.
The Price of Personalization

In an article in Proto magazine, published by Massachusetts General Hospital, PMC President Edward Abrahams comments on how personalized medicine is impacting patient care. “Personalized medicine has made significant progress in reshaping the way we think about how medicine should be practiced,” Abrahams said. The article notes that the concept of personalized medicine promises to replace “one-size-fits-all” drugs made to treat broad swaths of patients with new medicines designed to pinpoint genetic mutations and other molecular abnormalities that occur within patient sub-populations. It also points out that many of these drugs come with high price tags, making them contentious in the current environment despite their obvious value to patients. Proto (June 2014)

Drugmakers find breakthroughs in medicine tailored to individuals’ genetic makeups

In an interview with The Washington Post, PMC President Edward Abrahams discusses the process and cost of developing more personalized therapeutics. Abrahams notes the development of targeted drugs simply does not come cheap. Getting a promising drug to market can take a decade or more, he said, noting that unless companies can recoup those costs, research will wither. “As a society, we’re conflicted about this,” he says, adding that everyone wants to cure cancer and other diseases, “but at the other end, we have to be willing to pay for these products ... When you develop a drug for a segmented population, the cost of that drug is likely to be higher than if it worked for everybody.” The Washington Post (June 1, 2014)

Personalized Medicine: From Bench to Bedside

PMC President Edward Abrahams talks with PharmaVOICE about the future of personalized medicine. The story says personalized medicine will become standard in every hospital, clinic, and medical practice supported by electronic records, decision support systems, and tests that analyze disease for specific genetic markers. “My guess is that almost all the drugs in oncology have companion biomarker strategies incorporated into their development plans,” Abrahams says. “It’s been well-understood that cancer is a genetic disease. In order for these drugs to receive approval, they have to be effective and to be effective they have to target segmented populations. We’re seeing an increased commitment from the industry, especially in oncology, to personalized medicine.” PharmaVOICE (June 2014)

What is Personalized Medicine?

PMC President Edward Abrahams discusses reimbursement issues related to personalized medicine with Genome magazine. If a treatment or drug is outside medical guidelines, reimbursement is unlikely, he noted. “Medicine needs to be evidence-based,” Abrahams says. “Reimbursement is right up there with research in terms of priorities.” Genome (May 2014)

Tailored Medications Could be Just the Prescription

In a letter to the editor, PMC President Edward Abrahams discusses a Boston Globe op-ed, “Cure for some could cost us all: Tailored medications risk unintended financial consequences.” “By targeting drugs to patients based on their molecular profiles, personalized medicine allows physicians to concentrate therapeutic interventions on those who will benefit, sparing expense and side effects for those who will not,” Abrahams’ letter contends. “This is the future of medicine.” The Boston Globe (April 3, 2014)

Plavix Suits Target Personalized Medicine

PMC President Edward Abrahams discusses the recent lawsuits over Plavix (clopidrogel), which threaten to turn personalized medicine into a weapon against the biopharma industry, in this article from Genetic Engineering & Biotechnology News. Abrahams believes the Plavix lawsuits are unlikely to slow down personalized medicine by making biopharma companies reconsider developing new drugs for subsets of the general population. “It may even have a positive impact because the pharmaceutical companies will understand that it is in their collective interests to share noncompetitive data,” he said. Genetic Engineering & Biotechnology News (April 3, 2014)

Market-based Reimbursement Provisions for Lab Tests in HP 4302 Passes Senate with Industry Backing

In this GenomeWeb article, PMC Executive Vice President Amy Miller discusses the Senate’s passage of HR 4302, the Protecting Access to Medicare Act of 2014, which comes amid a plethora of reimbursement changes for the diagnostic industry. “I like to think of the diagnostics industry as [having] four parts: the sole-source labs, hospital-based pathologists, large clinical labs, and diagnostic kit manufacturers,” Miller said. “They’re quite varied and they don’t always agree, but they seem to on this.” GenomeWeb (April 2, 2014)
PMC summarizes its progress and outlines the challenges it will face in the coming years. PMC foresees three major challenges on the horizon:

- Imminent federal pricing of highly innovative molecular tests
- Inconsistent standards and paradigms for evaluating diagnostic, prognostic, and predictive genomic tests
- Lack of incentives for genomic medicine

PMC’s call to action is to monitor, evaluate, and contribute to the debate in these three areas to ensure that personalized medicine is integrated into the development of Medicare policy in the years ahead.

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THE CASE FOR PERSONALIZED MEDICINE

The fourth edition of PMC’s signature document, *The Case for Personalized Medicine*, is now available for download.

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MISSION: The Personalized Medicine Coalition (PMC), representing innovators, scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system. The Coalition’s mission is to educate policymakers and the public about the power and potential of individualized health care and raise the profile of personalized medicine so that both patients and the health system will benefit from improved clinical care and increased overall value.