

Research Reveals Public Attitudes Towards Personalized Medicine



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DEVELOPMENTS IN molecular biology, including the sequencing of the human genome, and subsequent advances in personalized medicine have generated excitement in the biopharmaceutical research and medical community. Experts see these advances as “revolutionizing” our understanding of disease and treatment approaches, ushering in a “paradigm shift” in patient care and a

“new era” in the practice of medicine.

New research sponsored by the Personalized Medicine Coalition finds that even the most knowledgeable consumers are largely unaware of these advances. But the public is very interested, and the more it learns, the more excited it becomes. The research also finds that the way experts explain personalized medicine can either generate excitement or alarm.

Awareness of Personalized Medicine

Both studies found that consumers were largely unaware of “personalized medicine.” Among leading-edge focus group participants, KRC, the agency PMC employed to conduct the survey found just eight of 52 had heard the term—and only two were able to describe it accurately. Similarly, GfK

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Profits and Progress

BY EDWARD ABRAHAMS

“Well, that’s lovely,” exclaimed Justice Antonin Scalia during oral arguments in *Association for Molecular Pathology v. Myriad Genetics* in response to the plaintiff’s lawyer’s contention that

fame will incentivize research and development in the future if gene patents were struck down. Justice Elena Kagan had asked the attorney if we should be concerned that in a world without intellectual property protection, companies might say, “Well, you know, we’re not going to do this work any more.”

Clearly, Justice Scalia was not buying the argument that “recognition” could drive innovation, and the Supreme Court was careful to underline that its decision in *Myriad* prohibiting gene patents did not apply to “complementary DNA,” or when something new had been created—thereby protecting one of the foundations of the biotechnology industry.

Because it opened up clinical research into previously closed off areas, most people in the personalized medicine community concluded that the *Myriad* decision was on balance

a net positive. But others pointed out that the case itself reflects a growing bias against industry with implications for innovation in the future.

Writing on the opinion pages of the *New York Times*, for example, Eleonore Pauwels, a researcher in Science and Technology Innovation Program at the Woodrow Wilson International Center for Scholars, argued that gene patents were only part of the problem. More “vexing,” according to her, are the trade secrets companies use to protect their investments. She called on the U.S. Food and Drug Administration to mandate disclosure of trade secrets as a condition for market approval, not noting that it has no such authority nor does it even regulate most diagnostic tests.

Also in the *New York Times*, the influential Columbia University economist, Joseph Stiglitz, opined that the “artificially high” price of diagnostics,

presumably because they enjoy patent protection, contribute to the growing inequality in the health of population. Leaving aside the fact that most diagnostic tests do not enjoy patent protection, a problem for an industry that has difficulty attracting capital because its profit margins have been so low, Stiglitz’s contention that capitalism and health are inversely correlated carries a lot of political freight.

But these opinions, stimulated by the *Myriad* decision, are only the tip of the iceberg that could stymie the innovation upon which personalized medicine depends. Americans, especially, have come to expect that innovation is a birthright, but the United States has done little lately to encourage innovation, notably by integrating diagnostics and therapy, even though doing so would improve health of patients and benefit our health system as well.

In fact, Washington is moving in the wrong direction.

First, though this might be the most promising era in the history of science and medicine, both political parties have decided to cut funding for the National Institutes of Health, not

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Following the creation of meaningful incentives to encourage industry investment, 440 so-called “orphan drugs” have secured FDA approval.



NINTH ANNUAL BOSTON RECEPTION

The Personalized Medicine Coalition invites you to attend a networking cocktail reception to kick off the 9th Annual Personalized Medicine Conference at the Harvard Medical School.

.....

Join the personalized medicine community at the Boston Museum of Science and
Preview the New *Hall of Human Life* Exhibit.

Set to open in late November, the *Hall of Human Life* exhibit, aims to revolutionize how people understand their own biology by investigating how humans change over time in our dynamic environments.

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Tuesday, November 5, 2013 • 6:30 – 9:30 p.m.

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Registration is free for PMC members, press and government;
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Cost-containment and Deficit Reduction Policy Principles

THE UNITED STATES government is facing pressure to control federal spending and lower the national debt, with health care costs as a focal point of debate to address this pressure. The path that policymakers take will have a significant impact on continued biomedical progress, the role of U.S. companies as global leaders in life science innovation, and the quality of patient care and physician choice.

To ensure that cost-containment policies do not undermine personalized medicine and protect innovation, the physician-patient relationship, and patient values and choice, the Personalized Medicine Coalition (PMC) released its policy principles. These principles seek to foster innovation in health care through policies that promote better and more effective health care while potentially lowering overall cost.

FDA Publishes Draft Guidance on Breakthrough Therapies

FDA has announced the availability of draft guidance for industry entitled “Expedited Programs for Serious Conditions—Drugs and Biologics.” The purpose of the guidance is to

provide a single resource for information on FDA’s policies and procedures related to expedited drug development and review programs that are intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions.

The Personalized Medicine Coalition submitted comments on the Centers for Medicare & Medicaid Services (CMS) Gapfill Payment Amounts, Clinical Laboratory Fee Schedule (CLFS).

PMC believes that the proposed molecular diagnostic gapfill payment schedule is deficient in that it:

- Threatens the future of personalized medicine by not addressing unintended consequences of the proposed gapfill payments;
- Confuses stakeholders due to the lack of transparency in the gapfill process; and
- Negatively impacts the quality of patient care and patient access to proper diagnostics and treatment.

Amy Miller, Ph.D., Vice President, Public Policy stated, “Coverage and payment decisions should be separate

processes. When CMS decides to cover a test, the payment should reflect the reasonable cost of performing that test, as well as covering the associated research and development costs and capital returns required to attract innovators to the industry.”

You may view PMC’s full comment letter on our website.

Response to FDA Commissioner Remarks on New Diagnostic Test Regulations

The Food and Drug Administration Commissioner Margaret Hamburg stated that the FDA “is working to make sure that the accuracy and clinical validity of high-risks tests are established before they come to market,” prompting widespread speculation into whether hers was a signal that the FDA intends to move forward with plans to regulate some laboratory developed tests (LDTs). Following Hamburg’s announcement, the American Clinical Laboratory Association (ACLA) issued a “Citizen Petition” asking the FDA to refrain from issuing guidance to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act, and to confirm that LDTs are

These principles seek to foster innovation in health care through policies that promote better and more effective health care while potentially lowering overall cost.

not devices as defined by the Act. In an informative interview, Alan Mertz, President of ACLA, outlined the trade association's position. Miller stated in *GenomeWeb*, "Personalized medicine is improving patient quality at an unprecedented speed."

HHS Office of Inspector General Releases Report, Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings

The HHS Office of the Inspector General (OIG) conducted a study, in June 2013, of 20 lab tests on a

Coverage and payment decisions should be separate processes. When CMS decides to cover a test, the payment should reflect the reasonable cost of performing that test.

fee-for-service basis to compare Medicare payment rates to those of other health care service payers. The controversial report found that "in 2011, Medicare paid between 18 and 30 percent more than other insurers for 20 high-volume and/or high-expenditure lab tests. Medicare could have saved \$910 million, or 38 percent, on these lab tests if it had

paid providers at the lowest established rate in each geographic area." The OIG "recommend[s] that CMS seek legislation that would allow it to establish lower payment rates for lab tests and consider seeking legislation to institute copayments and deductibles for lab tests." The complete report can be found on PMC's website.

Profits and Progress

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recognizing that investments in basic research are the keys to better health, if not prosperity in the future.

Second, while FDA is laboring mightily to encourage the development of personalized medicine by, for example, fast tracking "breakthrough therapies," its sister agency, the Center for Medicare & Medicaid Services, has issued a proposed revised clinical laboratory fee schedule that will neither pay for the cost of conducting a test in many cases nor the cost of the research and development that created it. The unintended consequence of CMS's cost-saving proposal, as PMC wrote in its letter to the agency on the scheduled "gapfill payment" policy, will be to place the field of personalized medicine in doubt.

Third, as part of tax "reform" proposals currently being considered by the Senate Finance Committee, the Orphan Drug Act of 1983 which provides a fifty percent tax credit and a seven-year market exclusivity to pharmaceutical companies that develop drugs for populations of less than 200,000, along with other tax-based industry incentives, could be on the chopping block.

It is worth considering the latter as we think about the future of personalized medicine.

In the early Eighties, the U.S. Congress recognized a problem. If pharmaceutical companies could not derive a profit from their investment in research and development of drugs for small populations, they would not do so. Following the creation of

meaningful incentives to encourage industry investment, 440 so-called "orphan drugs" have secured FDA approval, including the first personalized medicine to treat cystic fibrosis, along with other life-saving targeted therapeutics for lung cancer, melanoma and tuberculosis. These drugs, while expensive to be sure, have saved the lives of countless patients and also, incidentally, created a number of innovative companies that specialize in rare diseases.

What can we learn from this?

The lesson is clear. While market forces may not be fully appreciated and may, without government mediation exacerbate some societal issues, if we want to encourage innovation and progress unleashing them is probably a good idea.



The Buck Stops Here

BY AMY MILLER, VICE PRESIDENT, PUBLIC POLICY

Personalized medicine faces many challenges in science, business, and policy. Yet none have seemed as threatening to innovation or the future of healthcare quality as the recent policies to cut payment

levels for molecular diagnostics. While on its surface, payment levels for molecular tests may seem to be only a diagnostic industry issue, they impact drug selection, hospitalization, the quality of patient care, and the future of personalized medicine.

In July, PMC sent a letter to the Centers for Medicare & Medicaid Services (CMS) Gapfill Payment Amounts, Clinical Laboratory Fee Schedule (CLFS) expressing concern that the low draft payment amounts threaten the sustainability of the laboratory industry and continued investment in the developing field of personalized medicine. Like the CMS's overturned decision not to pay for certain personalized medicine tests late last year (Multianalyte Assays with Algorithmic Analyses or MAAAs), its new draft policy could have devastating unintended consequences.

In our letter we argued that these lower payments could:

- Halt drug-diagnostic company collaborations which will impede the development of targeted therapies;
- Discourage investment in the life sciences; and

- Trigger job loss in the science and technology sector.

PMC expressed immense concern with the problem-fraught process through which these prices were set. CMS provides coverage to the American people through 11 local contracts—all private insurance plan companies. CMS asked each of them to determine a price for the new molecular diagnostic codes that replaced an older way of paying for personalized medicine testing. CMS used those prices to develop draft national ones; yet there remained problems with “price non-independence,” transparency and process.

- Price non-independence: Some of the local contractors pegged their prices to another local contractor's prices thus begging the question: how can CMS use non-independent local prices, to set national ones?
- Transparency: It is unclear how much of the available data was used by the local contractors to determine new prices. Did they have access to most of the available data or only a bit of it? If only a bit, how does that skew payments?

- Process: Some local contractors did not set prices for some of the tests; yet no clarity has been given by CMS as to how that will factor into national price-setting. This also triggers a process question. For CMS, coverage and payment decisions are separate and distinct processes. By not setting a price, are local contractors making a *de facto* coverage decision to not cover particular tests? If so, PMC argues, this process must be repeated to keep the integrity of each separate process intact.

PMC asked CMS to conduct the pricing exercise used to develop the draft molecular diagnostic payment amounts again. We asked that CMS engage more stakeholders in a transparent, open process that should result in payment levels that are in-line with the actual cost of developing, validating, conducting, and sometimes interpreting molecular diagnostics, which represent the cutting edge of innovations in medicine.

Final prices from CMS are expected in the fall. After they are announced, the community has the opportunity to ask that a specific

price for a specific test be re-priced. We expect that the considerable outcry from the community will likely result in prices for some molecular diagnostics to enter a “reconsideration” process.

Deficit reduction attempts by CMS, like those described above, have resulted in strong advocacy by the diagnostics community members who have been asking Congress to slow, if not reverse, these decisions.

This landscape served as backdrop for PMC’s successful, standing-room only, Congressional briefing, *Personalized Medicine: How Medical Progress Happens*, hosted by Senator

Tom Carper (D-DE). Designed to educate policymakers who are considering how to assure medical progress tomorrow while managing today’s budget, those in attendance were urged to protect innovation and the future of health care. Speakers described how personalized medicine results in a better, more efficient system of care and how policy can support or hinder it. (see pg. 18).

Given that payment is where the buck stops, PMC has a number of projects to address these issues. First, we are updating our domestic reimbursement paper which we will publish early next year. Second,

following our successful summit with the Biotechnology Industry Organization, we are developing *Evidence, Coverage, and Incentives* a “playbook” for evidence that innovators can provide to payers to justify coverage and payment decisions that reflect the true cost of personalized medicine diagnostics including research and development, and test conduct, validation, and interpretation.

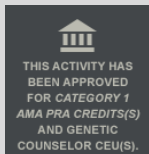
While some issues divide us, members of the Personalized Medicine Coalition are united in their vision that a strong, vibrant, and creative diagnostics industry is imperative to support personalized medicine.



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Research Reveals Public Attitudes Towards Personalized Medicine

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Bridgehead, which conducted its own analysis, found 73 percent had never heard the term, and only four percent who had heard it were able to correctly describe what personalized medicine is.

Unaided Impressions

KRC found that, although “leading-edge”, or knowledgeable consumers were unfamiliar with the term, they had a favorable impression of it at first glance. The term by itself evokes three key ideas:

- Highly individualized and proactive “concierge” medical care;
- Having more choices and control over one’s medical care and the ability to customize care or insurance based on specific family and medical history and personal needs; and

- Having access to a personally preferred family doctor.

One focus group participant said: “The first thing that popped in my mind was my family doctor and I’m thinking, Marcus Welby, MD, or someone like that, that has been around for years and years.”

In other words, while the term, “personalized medicine” evokes warm and fuzzy feelings, it does not convey what scientists mean when they use the term. The good news for personalized medicine proponents, though, is: participants think personalized medicine sounds like something positive.

Definition

The way personalized medicine is defined can significantly impact consumer receptivity. The good feelings evoked by the name, “personalized medicine,” evaporated in the focus

groups when it was defined as the President’s Council of Advisors and Science and Technology (PCAST) did in 2008.

According to PCAST, *“Personalized Medicine” refers to the tailoring of medical treatment to the individual characteristics of each patient...to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventative or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not.*

Focus group participants reacted negatively to this definition. Although the idea of tailoring treatment to the individual was appealing, the rest of the definition raised questions and anxiety. Thinking about being classified into subpopulations made people feel the opposite of personal; it felt to them that they were being put into boxes. For some people, it even brought up echoes of racism.

As one participant put it, “It doesn’t convey a dictionary definition of personal, or anything that’s personalized. It makes it sound like we’re going to sell you personalized and it’s really a subgroup, which you could call subgroup medicine—that would be a much better term. So, I think if they were trying to sell this as a term and fool you, and once you got in, you would find out that it had nothing to do with being personalized.”

About the research

On behalf of PMC, KRC Research conducted six focus groups among opinion-leading consumers in February 2013, two in each of three locations: Washington, D.C. (“inside-the-beltway”), Chicago and Dallas (“Main Street”). The research included a total of 52 participants—half Republican and half Democratic. Opinion-leading consumers follow what’s going on in the world and regularly discuss politics and current events, and so they are a good bellwether for gauging awareness of and attitudes toward “hot” topics. They also are a good group for testing the effectiveness of communications.

GfK Bridgehead from February 26 to March 4, 2013, also conducted a national online opinion survey among U.S. adults age 30 and older to measure awareness and attitudes about personalized medicine.

An alternative definition was proposed:

“Personalized medicine” is an emerging field of medicine that uses diagnostic tools to identify specific biological markers, often genetic, to help assess which medical treatments and procedures will be best for each patient. By combining this information with the individual’s medical history and circumstances, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans.

People who saw the new definition responded positively, saying it was clear, easy to understand, and consistent with the term. Nothing in the definition caused alarm.

But the definition left participants asking many questions about exactly what IS personalize medicine. The name and definition alone did not adequately convey what proponents of the paradigm are so excited about.

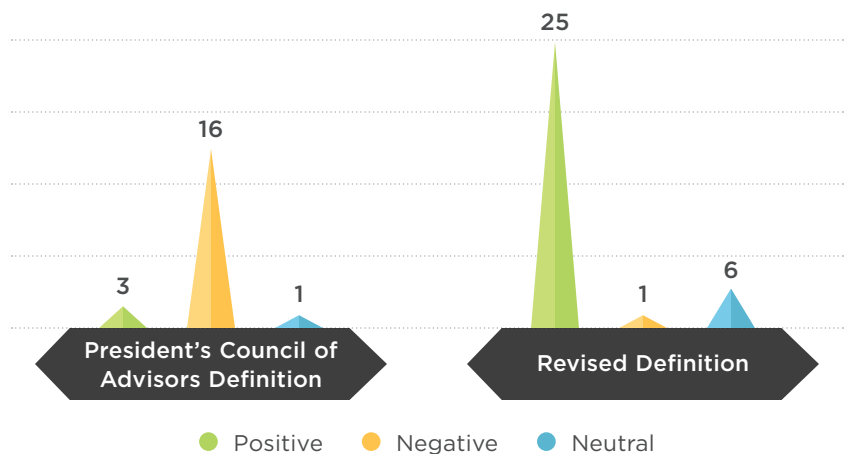
The Power of Examples

Examples are far more effective in explaining what personalized medicine is and in conveying its potential value. When focus group participants were presented with four current examples of how personalized medicine is currently used, people responded more positively than negatively to all the examples, but some examples generated more excitement while others evoked more fear.

For example, focus groups were told:

Physicians now can use a genetic test to help them determine the right dose of the blood thinner Warfarin, which is used to prevent strokes and heart attacks, for each of their patients. Doctors can determine if the patient metabolizes the drug more

Different Definitions, Different Reactions



Reactions to PCAST and revised definitions of Personalized Medicine were dramatic. People who saw the new definition responded positively, saying it was clear, easy to understand, and consistent with the term.

quickly or slowly than average. People who metabolize it more quickly eliminate the drug from their body before it has a chance to work, and therefore require a higher dose. People who metabolize it more slowly build the drug up in their bloodstream, leading to an over-dose. It is important to get the right dose of this drug for each patient to avoid complications from too low a dose (like blood clotting) and too high a dose (like internal bleeding).

When participants read this example, they were skeptical. What stood out for them were the high risks associated with blood thinners. Participants discussed personal examples and some horror stories about blood clots and bleeding. The fears overwhelmed the message—which was about regulating the dose and minimizing side effects.

The examples that communicate the value of personalized medicine

most clearly and which get people visibly excited are ones about familiar diseases where personalized medicine can offer less intrusive diagnostics; clear-cut or at least helpful information to guide and improve decision-making, thus helping get to a diagnosis faster; less difficult treatments, and better outcomes. For example, people had more positive reactions to Herceptin.

There is a breast cancer treatment called Herceptin that is very effective for women whose tumors “over-express” a certain type of protein called “HER-2” protein, which can be identified through a genetic test. Twenty-five percent of women with breast cancer have this form. As a result, for these women, Herceptin dramatically improves their odds of survival and reduces the chances of disease recurrence. For other women, this specific drug does not have a beneficial effect; therefore their doctors can recommend

different treatment regimens instead.

The example works, according to analysis, because it seems to offer clear direction—not more information that you might not know what to do with.

In brief, focus group participants were interested in:

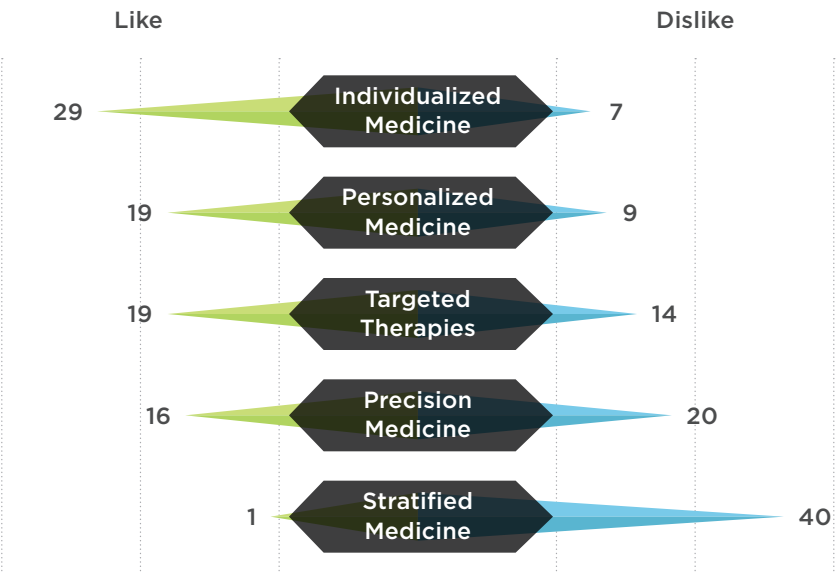
- More proactive care: better detection, prevention, and earlier intervention;
- Reducing the amount of trial and error, thus getting to effective treatment sooner; and
- Less invasive procedures and reduced side effects of treatments.

“Leading-edge” consumers were also excited that fifty percent of drugs in the biopharmaceutical pipeline are targeted and that personalized medicine is not a pipe dream; it is already here and the possibilities are growing. As one person put it, “To me, it almost indicates that there might even be more research when we’re looking at biological markers and when we’re looking at genetics. We’ve got some diseases now that we’re moving forward on but we’re not there yet. And if this would get us moved forward on some of those, I think that would be a huge positive step.”

Privacy, Access, and Personal Choice

One concern about personalized medicine is cost. On one hand, people worry that personalized medicine may

Survey of preferred name for “Personalized Medicine”



By far, the two favorite names were “individualized medicine” and “personalized medicine.” The word, “targeted” was also a favorite. “Precision medicine” was more negative than positive; and “stratified medicine” was disliked most of all.

drive up health care costs. On the other, they think the focus on preventive and targeted treatment with better outcomes could lower costs and improve outcomes in the long run. Either way, consumers want access.

The cost issue is directly linked to access fears. Consumers worry that if insurers won’t cover personalized medicine, they won’t be able to afford it. That would make personalized medicine a luxury medicine that only the wealthy can afford.

Consumers are very clear about who should ultimately make decisions about their personal health and treatment decisions: they should, with the guidance and direction of their doctors. Consumers are aware of and sympathetic to the pressing need to contain costs. Yet, they have little sympathy in the face of potential denied coverage for a treatment their doctor says is right for them. This is a big fear.

Thus, people were concerned

“Leading-edge” consumers were also excited that fifty percent of drugs in the biopharmaceutical pipeline are targeted and that personalized medicine is not a pipe dream; it is already here and the possibilities are growing.

about who would have access to their personal information—and if access to personal information could be used against them. One participant said, “I’m concerned about the privacy issues. Who gets this information and what’s the insurance company going to do with this? Are they going to raise my rates simply because my grandfather had bone cancer?”

Patients worry insurers might not cover treatments that could help them because their odds are low—but if they have no other options they may want to fight the odds. So they have questions about whether there are protections in place to provide access.

In the GfK survey, one question asked consumers what they would do if diagnosed with a life-threatening cancer and a test told them a drug wouldn’t work. Thirteen percent said they would try to get the treatment anyway, 71 percent said they would get a second opinion, and only 13 percent said they would accept the result.

Consumers, the studies discovered, may be willing to share some costs. The GfK survey for example found that people would be willing to pay for some testing out of pocket. “If it works, patients are willing to share the costs,” Susan Garfield, the study’s author, says. Many would pay \$500 for a test—if it has a big effect on their chances of surviving a serious disease.”

Partisan “No Man’s Land”

Although many issues divide along partisan lines, the research found that this wasn’t the case for personalized medicine, a significant attribute. Little difference was found

in how Democrats and Republicans talked and felt about personalized medicine. While Democrats focused more on access and preventive care, Republicans focused more on personal responsibility. But overall, Democrats and Republicans had most of the same hopes and fears about the development of personalized medicine.”

Names

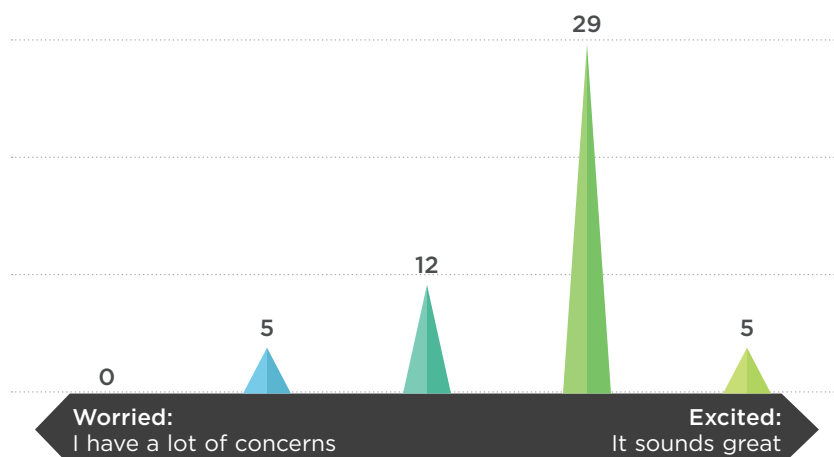
At the end of the focus groups, participants were to pick the names they liked and thought best described the topic from a list of names use to describe personalized medicine. By far, the two favorite names were “individualized medicine” and “personalized medicine.” The word, “targeted” was also a favorite. “Precision medicine” was more negative than positive; and “stratified medicine” was disliked most of all.

Consumer Demand

For now, consumers are not aware of the breakthroughs that have so many in the field excited. But as personalized medicine evolves and is introduced more widely into everyday medicine, consumers seem positioned to embrace it. And if they learn more about it, they may even demand it.

Despite questions about privacy and access, people clearly want personalized medicine. People were so excited about the potential benefits that their biggest fear was getting left out. After learning more about personalized medicine, nearly 80 percent of the participants in the focus groups felt that insurers should cover personalized diagnostics and treatments, even if there is a high up-front cost, which they were willing to share.

Hope and Fears of Personalized Medicine



The majority of those surveyed feel excited about personalized medicine. The biggest concerns were regarding cost and access to treatments. The most exciting ideas were around better more informed tailored treatment options.

Personalized Medicine Coalition Recognizes Kathy Giusti with Award for Leadership

Ninth Annual Personalized Medicine Coalition Conference
2013 Leadership in Personalized Medicine Award

THE PERSONALIZED MEDICINE COALITION (PMC) will present Kathy Giusti, Founder and CEO of the Multiple Myeloma Research Foundation (MMRF) with its 2013 Leadership in Personalized Medicine Award for her inspirational work in advancing personalized medicine.

According to Stephen Eck, M.D., Ph.D., Vice President, Astellas, who nominated Giusti for this year's recognition, "Ms. Giusti's seminal contribution to personalized medicine comes from her own experience as a patient with multiple myeloma. Her vision of blending philanthropy-funded research while employing sound drug development business practices enhances the likelihood of success in these endeavors. Her leadership, vision and personal commitment to this field will help generations of future patients."

Kathy Giusti is the Founder and Chief Executive Officer of the Multiple Myeloma Research Foundation (MMRF) and the Multiple Myeloma

Research Consortium (MMRC). Shortly after being diagnosed with multiple myeloma, she founded the MMRF in 1998 to stimulate innovative multiple myeloma research and drug discovery. She then founded the MMRC, enabling leading research institutions to work with industry to speed the discovery and development of effective new treatments for multiple myeloma.

"I have known Kathy for more than 15 years and find her to be truly inspirational. No other individual has had as significant impact in the research and treatment of multiple myeloma as Ms. Giusti," said William S. Dalton, Ph.D., M.D., Director, Personalized Medicine Institute, Moffitt Cancer Center and CEO, M2Gen who also nominated Giusti for this year's award. "Ms. Giusti's business acumen and passionate desire to find cures have established an unprecedented approach to multiple myeloma research, education and funding that has changed the



Kathy Giusti, Founder and CEO of the Multiple Myeloma Research Foundation (MMRF)

landscape for generations to come. Indeed, Kathy's success has been an inspiration and model for many patient advocacy groups and foundations dedicated to eliminating death and suffering due to many diseases. Her contributions exemplify the very purpose of the PMC Leadership in

Ms. Giusti's business acumen and passionate desire to find cures have established an unprecedented approach to multiple myeloma research, education and funding that has changed the landscape for generations to come.

Personalized Medicine Award,” continued Dalton.

“PMC’s recognition of our innovative approach to advancing the promise of personalized medicine means a great deal to all of us at the MMRF,” said Ms. Giusti. “I am deeply humbled by this honor, and accept this prestigious award on behalf of the entire team and

our many visionary partners, who have enabled our success.”

The PMC Award recognizes an individual whose contributions in science, business, and/or policy have helped advance the frontiers of personalized medicine.

The award will be presented at the Personalized Medicine Conference

at Harvard Medical School on November 6, 2013 in Boston, Massachusetts at which Ms. Giusti will deliver an address on her vision of personalized medicine.

To register for the conference, please visit <http://pcpgm.partners.org/educational-programs/personalized-medicine-conference/registration>

PERSONALIZED MEDICINE REGULATION

PATHWAYS FOR OVERSIGHT OF DIAGNOSTICS



While the potential benefits of personalized medicine health care are straightforward—knowing what works, knowing why it works, knowing whom it works for, and applying that knowledge to address patient needs—the intervening variables that determine the pace of personalized medicine’s development and adoption are far more complex. Among those variables are the laws and regulations that govern personalized medicine products and services used in clinical practice.

Download a copy by visiting personalizedmedicinecoalition.org

Reed Tuckson on the Health Care Crisis

Remarks by Reed Tuckson, M.D.

Following is an excerpt from a keynote address by Reed Tuckson, M.D., Managing Director, Tuckson Health Connections and Former Executive Vice President and Chief of Medical Affairs, UnitedHealth Group on April 17, 2013 – Washington, D.C. at the PMC/BIO “Evidence, Coverage and Solutions Summit.”

It is a privilege to have this opportunity to set the context for this important meeting on evidence, coverage and incentives for new biomedical innovations.

To begin, it is essential that we focus on the overarching objectives and larger purposes of what we collectively are trying to achieve. There is no question that every stakeholder along the continuum of care is going to have to approach the increasingly urgent challenges of this historical moment in innovative ways. As such, all of us need a unifying vision that keeps us grounded in our purposes and that provides an opportunity for coherent and leveraged strategies that will ultimately lead to the optimal health for the people of our nation.

Most of us have now accepted that the “Triple Aim,” first advanced by the Institute for Healthcare Improvement, provides a useful construct. The goal of improving the health of the population; enhancing the patient experience with care (quality, access and reliability of care delivery); and reducing the per capita cost of care is reasonable and functional.

This vision exists within the context of at least four major contextual challenges; I will elaborate on two:

1. The unsustainable crisis in cost escalation.
2. Suboptimal quality of care and the waste of increasingly expensive assets.
3. The explosion of preventable chronic illness that delivers increased numbers of sick people into an expensive and complex delivery system.
4. A fragmented and uncoordinated medical and medically-necessary social support delivery system.

First: Cost Escalation.

Cost escalation is now so severe that it is not possible in any meaningful way to continue to pay more in health care expenditures. We have hit the ceiling. America’s largest employers

are almost at the end of their rope and, for sure, small businesses have maxed out on their ability to handle any more cost escalation.

There’s nowhere else to go with Medicare, especially with sequestration and the reluctance to increase taxes. And state government budgets are similarly overwhelmed, especially with the escalating costs for Medicaid and state employee health insurance.

So, as costs escalate, the only place to get money is from the pockets of the American people. Out-of-pocket health care costs are skyrocketing while wages remain flat. So when you are thinking about the grand innovation that you want to introduce, remember that somebody is going to have to pay for it and, increasingly, it will mean the pocketbook of Mrs. Jones on 43rd and Vine.

Second: The Misuse of Healthcare Assets.

Make no mistake about my respect and admiration for this nation’s physicians and health professionals. Unfortunately, medicine has gotten extraordinarily complex to deliver, both in terms of the complexity of the science and its translation into

Cost escalation is now so severe that it is not possible in any meaningful way to continue to pay more in health care expenditures. We have hit the ceiling.

clinical interventions and the inter-relationships between a complex and fragmented delivery system.

Purchasers of care are reacting by giving individual consumers/patients “skin in the game” that incentivizes them for making personally appropriate and cost-effective choices and decisions. There will be no more blank checks that enable people to go to any doctor or any hospital or receive any diagnostic or therapeutic intervention without regard to clinical appropriateness, quality/cost-effectiveness of care delivery.

Relatedly, the delivery system is being reimbursed based upon the quality and cost-effectiveness of the care provided. In other words, “value” will be the watchword for both health benefit design and delivery system reimbursement.

The “fee-for-service” reimbursement system is dying a slow death. No purchaser of care is interested in paying physicians and hospitals for piecemeal. With each passing month, we are moving inexorably forward in aligning reimbursement with the demonstrated outcomes of the total care management for populations of patients.

Let me be clear, that while all of us must be focused on enhancing quality and reducing costs, it would be tragic and short-sighted if our preoccupation on these essential responsibilities resulted in killing off the golden goose of innovation. It is essential that we find new clinical approaches that will ramp-up quality and reduce health care expenditures. We need to encourage and support disruptive innovations that replace traditional

In the context of escalating drug costs, it is exciting that a \$400 test could avoid the waste and harm of an inappropriate \$40,000 chemotherapeutic drug.

expensive interventions and develop new value propositions based on new performance criteria. We need to identify and facilitate the introduction of interventions that optimize health outcomes at total costs of care that are lower than existing treatment. We have to make clinical care simpler and less complex to deliver and more convenient, more personal. We have to move hospital care to the outpatient setting and then move outpatient care to the home. We need more effective and accurate care; safer interventions that are less painful, uncomfortable and invasive; that are more timely; and that are targeted to organs, tissues, and cells.

The challenge before us collectively, is to efficiently produce the research that answers the important value-based clinical questions. We need to know how the innovation performs in the real world; not only in a research study.

Currently, the hierarchy of evidence used by most health plans begins with statistically robust, well-designed clinical trials; followed by, statistically robust, well-designed cohort studies; large multisite observational studies; single-site observational studies; and, finally, national consensus statements by recognized authorities such as NIH, AHRQ, United States Preventive Services Task Force, specialty societies, and expert opinion

using Cochran grading.

Observational studies, if carefully designed and contain robust data, can answer the important questions regarding treatment effect in real-world practice: does it do what it claims and is it safe?

Finally, given this meeting’s focus on personalized medicine, it is obvious that we will all benefit from getting to the molecular cause of disease. We want the right person to get the right therapy and the right dose at the right time. We want to be able to predict in advance which patient will respond to the intervention, and we want individualized therapy with medications that have a specific action target. In the context of escalating drug costs, it is exciting that a \$400 test could avoid the waste and harm of an inappropriate \$40,000 chemotherapeutic drug.

I appreciate the opportunity to share these thoughts with you. I urge you to keep your focus on solving critical problems, not gaming the system. We must remember that our nation’s future is dependent upon finding new things that work, that will drive up quality and take out cost, that can be appropriately implemented by physicians and hospitals who understand who is appropriate for what interventions and under what conditions.

Janet Woodcock on Personalized Medicine



JANET WOODCOCK, M.D., Director, Center for Drug Evaluation and Research at the Food and Drug Administration (FDA), delivered the keynote address at the Ninth Annual State of Personalized Medicine Luncheon in May hosted by the Personalized Medicine Coalition (PMC) at the National Press Club in Washington DC.

Attended by over 150 innovators, patients, scientists, and government officials devoted to the understanding and adoption of personalized medicine, Dr. Woodcock discussed how the FDA is dealing with the expanding field of personalized medicine, including its efforts to encourage its development.

“I am here to declare victory, the coming of age of this vision,” Woodcock stated. “Targeted therapies have reached the mainstream.”

But while personalized medicine has come of age, she noted that

the field still faces many challenges, including obtaining reimbursement.

Reimbursement for genetic tests is one of personalized medicine’s biggest challenges, and the FDA is seeing resistance to reimbursement for targeted therapies in some areas, which Woodcock said at the luncheon, is an obstacle to progress. We need to focus on showing how targeted therapies, even if they are more expensive, provide value to the health care system. “We need,” she said, “to combine treatments of developed and effective interventions that cure or control disease.”

But the main focus of her talk was what she argued was the antiquated

dependence on controlled randomized clinical trials. She said that future progress depends on “turning the paradigm on its head” to allow more specifically targeted, personalized drug therapies to get on the market faster. “We are going to have to change the way drugs are developed. Period.”

Dr. Woodcock concluded her address by noting that the path ahead won’t be easy and will require a “grand change” in the way clinical trials are organized by drug regulators and developers. “We’re going into uncharted waters here”, Woodcock said. “I think its going to be a big challenge for everyone.



Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research at the Food and Drug Administration meets with members of the press following her State of Personalized Medicine Address at the National Press Club.



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Personalized Medicine: How Medical Progress Happens



Stephanie Haney, patient advocate and beneficiary of crizotinib, tells her story to find treatment and arrest the spread of cancer in her lung.

TO EXPLAIN THE FOUNDATIONS of innovation, PMC convened an educational briefing entitled, *Personalized Medicine: How Medical Progress Happens*, in the Senate Visitor Center on July 22. Of the over 100 attendees in this standing room-only briefing sponsored by Senator Tom Carper of Delaware, about one third were Congressional staff.

Amy Miller, Vice President for Public Policy, presented the briefing's purpose: to introduce the concept of personalized medicine, explain how innovation occurs in medicine and

illustrate how public policies can help or hinder medical progress.

She was joined by four champions for personalized medicine, led dramatically by Stephanie Haney, a patient advocate and beneficiary of crizotinib after other trial and error, one-size-fits-all medications failed to arrest the spread of cancer in her lung. Haney emphasized that funding for corporate R&D in particular is critical for patients.

She was followed by Stephen Eck, M.D., Ph.D., Vice President, Oncology Medical Sciences at Astellas

Pharmaceuticals, who explained how drug development is changing by offering greater ability to predict, preempt, and cure life-threatening diseases.

Patrick Balthrop, CEO of Luminex, discussed the critical role of diagnostics in facilitating targeted therapeutics while pointing out that the future of companion diagnostics may be threatened by the proposed cuts in CMS payment schedules for molecular diagnostics, often below the cost of conducting the test, as well as the R&D that goes into developing them.

Finally, Amy Abernethy, M.D., Ph.D., an oncologist and Director of the Duke Center for Learning Health Care, explained how personalized medicine has changed the nature of clinical care, noting that future progress depends on our ability to aggregate data and make effective use of informatics.

Key statements from PMC's Cost-containment and Deficit Reduction Policy Principles that were released during the briefing include:

- A comprehensive shift away from health care based on population averages and towards patient-centered care is central to improving health care outcomes and addressing a patient's perception of value.
- A health system that focuses on care that is predictive, preemptive,

and preventive has the potential to revolutionize health care by allowing clinicians to individualize therapy for patients through the early diagnosis of disease and risk assessment in order to optimize clinical outcomes and to better manage patients before disease symptoms appear.

- Reform assessment tools (in particular, comparative effectiveness research and health technology assessment) must better align with emerging science and patient-centered health care.
- New payment models, such as accountable care organizations (ACOs) and bundled payments, which promote coordination and integrated care, hold potential to shift incentives to high-quality,

Policy solutions like those released by PMC are so important—many patients continue to face significant unmet medical needs that can be effectively, efficiently met through novel targeted therapies.

high-value care for patients.

However, if improperly designed, such models will set payment based on current standards of care and discourage advances in medical technology and medical practice

- There must be a continual learning system to aggregate, analyze, and apply evidence-based knowledge to patient care. PMC believes that health informatics and electronic health record (EHR) systems must be used to promote these systems

that which will help improve patient care, reduce costs, and accelerate the process of drug development.

Randy Burkholder, Vice President, PhRMA, noted that “policy solutions like those released by PMC are important. Many patients continue to face significant unmet medical needs that can be effectively, efficiently met through novel targeted therapies; [and] policy should provide adequate incentives for continued progress.”



Standing room-only attendance at PMC Hill Briefing on Personalized Medicine: How Medical Progress Happens.

Conference Highlights Pathway to Consensus On Clinical Evidence For Diagnostics

BRUCE QUINN M.D., PH.D., SENIOR HEALTH POLICY SPECIALIST, FOLEY HOAG LLP

EVIDENCE, COVERAGE,
AND INCENTIVES: A PMC/BIO
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IN THE LAST several years, it has become clear that the success of a new and molecularly based personalized medicine could bring together the cutting edges of science and clinical practice with a speed the healthcare system has probably never seen.

The key question is whether this will be accelerated or delayed, because the legacy systems for evidence review and reimbursement policy shift very slowly. Unless evidence and reimbursement decisions are coordinated, the incentives for personalized medicine will be lacking. On April 17, the Personalized Medicine Coalition (PMC) and Biotechnology Industry Organization (BIO) jointly hosted a multi-stakeholder Solutions

summit in Washington, DC on *Evidence, Coverage, and Incentives* attended by over 200 individuals. Speakers included payers, evidence assessment experts, providers, and representatives of health care businesses from both the pharmaceutical and diagnostic industries. They focused on practical solutions to the fragmentation of our healthcare system from the viewpoint of its adverse impact on personalized medicine.



Attendees enjoy the post Summit networking reception in Washington, DC

Reed Tuckson, M.D., Managing Director, Tuckson Health Connections and former Executive Vice President and Chief of Medical Affairs, UnitedHealth Group, vigorously called for action in his keynote address, emphasizing that U.S. health care was the world's most expensive, excessively wasteful, and must be reformed in a way that puts costs and quality first, as there is "not one more dollar," he said, to go into health care from the rest of the economy. He forecast a rapidly arriving new system where fee-for-service medicine disappears, and providers maneuver within a fixed-budget structure (see pg. 14).

Following Dr. Tuckson, a series of panels focused on evidence standards for payer coverage, evidence standards for clinical guidelines, and market access for companion diagnostics. In the payer panel, it was noted that in a capitated world, such as Dr. Tuckson envisioned, there may be less need for payers to make one-off coverage decisions, if payers transmit capitated annual payments to integrated health systems.

On the other hand, assuming that more granular coverage decisions continue, innovative programs like the Medicare regional MOLDX program are being watched closely. MOLDX has been piloted in California, where molecular tests must be submitted



(Left) Paul Landauer, Sr. Director at Abbott Molecular and (Right) Kelly Burgeson, Executive Director, Oncology, Boehringer Ingelheim, spoke on Market Access for Companion Diagnostics panel at the Summit.

with a new system of extremely granular codes, called "Z codes." Matt Zubiller of McKesson described this coding system, and proposed a more rational "playbook" for evidence assessment, based on accepted future evidence templates and evaluation standards for 10 to 15 standardized test types (such as "a metastatic cancer prognostic test"). Tamara Jensen of Centers for Medicare & Medicaid Service's (CMS) Coverage & Analysis Group emphasized that CMS looks to credible community guidelines and evidence standards wherever possible.

The second panel addressed the inclusion of diagnostics in society and technology assessment guidelines. Here, best practices are emerging

and not only is there greater evidence on objective evidence rather than expert opinion, but on public review and comment of draft assessments, as is currently done by the Agency for Health Research Quality, the United States Preventative Services Task Force, and other groups. It was emphasized that guidelines exist secondarily to impact payer decisions, but primarily to inform physicians of best practices and the positions currently held by expert consensus. It was also noted that historically, medical association guidelines were often reviewed on a five-year basis, whereas groups like National Comprehensive Cancer Network (NCCN) have learned how to update guidelines

Matt Zubiller of McKesson proposed a more rational "playbook" for evidence assessment, based on accepted future evidence templates and evaluation standards for 10 to 15 standardized test types.

more quickly based on rapidly developed cancer drugs and new indications which, it has contended, may be a better model for personalized medicine and diagnostics. However, the NCCN model requires a very substantial infrastructure and resources to maintain on a running basis.

During the mid-day lunch break, Dr. Louis Jacques participated in a question-and-answer session with the participants. Dr. Jacques noted that while it was clear genomic medicine was advancing rapidly, an issue for the Medicare program remains the need to decide when technologies are really ready for prime time, as signaled by the classic coverage decision and the beginning of reimbursement. CMS, he said, wants to ensure access for

While it was clear genomic medicine was advancing rapidly, an issue for the Medicare program remains the need to decide when technologies are really ready for prime time, as signaled by the classic coverage decision and the beginning of reimbursement.

appropriate technologies for Medicare beneficiaries, and is working to develop new channels to faster coverage through collaboration with the FDA—the “Parallel Review” program, Coverage with Evidence Development, and the opportunity to meet and discuss evidence with CMS staff prior to a market launch.

The third panel focused specifically

on companion diagnostics and market access. Again, the great need for physician education was emphasized. In some cases, FDA-approved companion diagnostics can appropriately be co-promoted in physician outreach and education for on-label drugs, but this is not true in every case.

One of the most telling anecdotes described a panelist’s recent encounter with the chair of surgery at a major institution who asked, “What is a KRAS?,” an anecdote he used to remind the audience of personalized medicine stakeholders that facts taken for granted in our community may be still be off the radar with clinicians and policymakers. Soon, cancer patients may be screened for very large panels of gene mutations using next-generation sequencing, and the route to “market access” through physician awareness will have new meanings, like electronic chart prompts for test orders and rapidly available online education on the implications of genomics for a patient’s.

The fourth and final panel was positioned to sum up the day by focusing directly on the role national initiatives to incentivize the development of personalized medicine



Paul Billings M.D. Ph.D., Chief Medical Officer at Life Technologies and PMC Board Member



(Left) Jamie Taylor, Senior Director, Johnson & Johnson. (Right) Summit organizers Amy Miller, VP of Public Policy, PMC and Paul Sheives, J.D., Director of Diagnostics and Personalized Medicine Policy, BIO.

diagnostics, including proposals to change the regulatory and payment systems for them. In addition, it was noted that patient and corporate collaborations are an equally important contributors. There was an extensive discussion, for example, of the Cystic Fibrosis Foundation's close and innovative participation in Vertex's development of Kalydeco®,

where “venture philanthropy” materially helped speed clinical trials of a drug for just a subset of cystic fibrosis patients with a particular gene defect.

The conference was closed by Amy Miller, PMC Vice President for Public Policy and Paul Shieves BIO Director of Diagnostics and Personalized Medicine Policy. They described an emerging view

of a “playbook” that could remove unnecessary barriers to the progress of personalized medicine. They said, there should be a clear statement of the required level of evidence across different domains, yet flexible enough to allow for new scientific developments. And, they concluded, there remains an important opportunity for innovative national legislation.

Soon, cancer patients may be screened for very large panels of gene mutations using next-generation sequencing, and the route to “market access” through physician awareness may have new meanings.

Personalized Medicine Coalition Elects New Board Member

Patrick J. Balthrop, president and CEO of Luminex Corporation was elected to the Personalized Medicine Coalition's board of directors for a three-year term.

"Pat will be a strong addition to the Coalition. As CEO of Luminex, an important player in the field of personalized medicine, his company has been on the forefront of developing innovative products that assist patients, including instruments and assays that make health care faster, more accurate and affordable. His leadership, notably in navigating the regulatory arena, will serve PMC well," said Stafford O'Kelly, former president of Abbott Molecular and current chairman of the PMC.

Mr. Balthrop joined Luminex Corporation as President and CEO in May of 2004. Prior to joining

Luminex, Mr. Balthrop was employed by Fisher Scientific International as President of Fisher Healthcare for two years. He spent 20 years in the medical devices and diagnostics divisions at Abbott Laboratories, successfully transforming several businesses and franchises. His product development career achievements include the introduction of the world's first blood test for HIV and leading the development of the most widely used immunoassay testing system.

"I strongly believe personalized medicine has the potential to improve patient care and am honored to serve on the Coalition's board. I am committed to working with its members on public policy issues to encourage its development," said Mr. Balthrop.



Patrick J. Balthrop, president and CEO of Luminex Corporation

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- *Plans for Implementing Personalized Medicine in Canada*, Pierre Meulien, Genome Canada
- *PhRMA's Outlook on Personalized Medicine*, William Chin, M.D., PhRMA
- *CMS Beneficiaries and the Role of Personalized Medicine in Improving American Healthcare*, Patrick Conway, M.D., MSc, Centers for Medicare & Medicaid Services; Center for Clinical Standards & Quality
- *Novel Solutions - Crowdsourcing: A New Approach for Innovation in Personalized Medicine*, Karim R. Lakhani, Ph.D., M.S., Harvard Business School; Harvard-NASA Tournament Lab at the Institute for Quantitative Social Science

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U.S. News & World Report: Best Hospitals Guidebook

The Personalization of Medicine, a feature article in this year's U.S. News & World Report Best Hospitals Guidebook discusses the maturation of personalized medicine over the past decade. PMC provided background for the article and Edward Abrahams, president of PMC, was quoted, "There are now over 80 personalized medicine treatments available." *U.S. News and World Report*

Bloomberg Chronicles PMC Initiatives

Bloomberg BNA chronicles PMC initiatives through a series of in-depth articles covering the the PMC/BIO Solutions Summit on evidence, coverage and incentives held in Washington, D.C.; the Ninth Annual State of Personalized Medicine Luncheon at the National Press Club in Washington, DC., with keynote speaker, Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research at the Food and Drug Administration; and the two day Diagnostics and Personalized Medicine Forum hosted by PMC and BIO.

Unhealthy Prognosis for Venture-Backed Diagnostics

Bruce Booth of Atlas Ventures outlines six "tough realities" facing the diagnostics industry, but acknowledges a few positive examples, stating, "The Personalized Medicine Coalition has certainly been a positive force for pushing the field around policy changes and more collaborative models." *Forbes*

Promise of Field Is Likely to Be Fulfilled As Business Models Change, Stafford O'Kelly Says

Stafford O'Kelly, chair of the Personalized Medicine Coalition (PMC), opened the Diagnostics and Personalized Medicine Forum held at the International BIO Convention, said that the promise of personalized medicine to transform health care will start to be fulfilled as business models change and reimbursement is made for products that work. *Bureau of National Affairs*

PMC/BIO Solutions Summit Summary

A summary of the *Evidence, Coverage and Incentives Summit* was published in Medical Device Daily describing how the conference brought together multiple stakeholders to engage outstanding issues, including how it will be possible to demonstrate that new products and approaches increase quality and decrease costs. *Medical Device Daily*

MGH, AstraZeneca Partner to Create New Drug Combinations

AstraZeneca and Massachusetts General Hospital have unveiled a new partnership to use the pharmaceutical company's growing library of drugs and the hospital's computer analysis to identify combinations of treatments for cancer patients. The collaboration between MGH and AZ is "very exciting and in keeping with a larger trend of targeting the right drugs based on a better molecular understanding of the patient's genetics and the physiology of the particular tumor," said Edward Abrahams, president of the Personalized Medicine Coalition. *Boston Globe*

FDA Rethinking Personalized Drug Trials

During her keynote address at the Ninth Annual PMC State of Personalized Medicine Luncheon at the National Press Club on May 21, Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research at the Food and Drug Administration (FDA), stated that the FDA will need to "turn the clinical trial paradigm on its head" in order to allow more specifically targeted, personalized drug therapies to get on the market faster. *MedPage Today*

FDA approves New Test That will Help Treat Hepatitis C

The Food and Drug Administration for the first time approved a diagnostic test, Abbott Realtime HCV Genotype II, which will allow doctors to determine what kind of hepatitis C virus an infected patient has and to tailor treatments accordingly. Edward Abrahams, president for the Personalized Medicine Coalition, noted that such tests demonstrate "where medicine is headed," adding that they can "reduce overall costs, as we won't have to prescribe one-size-fits-all treatment to all-comers." *LA Times*

Exclusive: A Tailored Approach

In an interview with *International Innovation*, a London based periodical, Edward Abrahams discusses the potential political, scientific and economic impact of personalized medicine on health care. He noted, "We need cooperation within the research community, between the diagnostic and pharmaceutical industries; and the regulatory and reimbursement systems should be better aligned to encourage investment so that new and better products may enter the market and patients benefit." *International Innovation*

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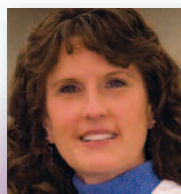
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The Personalized Medicine Coalition (PMC), representing innovators, scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and the health system.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



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