

# Right Drug–Right Patient–Right Time: Personalized Medicine Coalition

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**T**he right drug for the right patient at the right time is the mantra of personalized medicine. As Health and Human Services Secretary Michael O. Leavitt said at a meeting of the Personalized Medicine Coalition (PMC), an independent, nonprofit organization, on March 23, 2007, advances in science and technology have presented an unprecedented “opportunity to bring health care to a new level of effectiveness and safety.”

That vision, in the context of the challenges faced by patients and the entire healthcare system, encompasses a multifaceted program necessitating a range of activities. It calls for nothing less than investing in basic and translational science; integrating health information technologies so that data can be aggregated and applied; shaping new regulations that facilitate the co-development of diagnostic and therapeutic products; introducing reformed modes of payment and reimbursement that encourage the development of targeted therapeutics; and finally, reshaping education so that new knowledge will be useful for healthcare providers and patients.

To meet this challenge, the PMC was founded by a small group of pioneers in the industry and academia who recognized that personalized medicine could be transformational, not only by reshaping our understanding of biology but also by altering both the way drugs are discovered and developed and by changing the way medicine is practiced in the future. They also understood, however, that science alone—without the support of changes in policy and practice in both the public and private sectors—could not and would not lead to better medical outcomes for patients and improved efficiencies for the entire healthcare system.

## The PMC Today

The PMC, an educational and advocacy organization representing a broad spectrum of academic, industrial, patient, provider, and payer communities that share an interest in advancing the understanding and adoption of personalized medicine concepts and products, was launched in November 2004. The organization set forth four key goals:

- Provide leadership on public policy issues that affect personalized medicine;
- Help educate the public, policymakers, government officials, and private sector healthcare leaders about the public and personal health benefits of personalized medicine;
- Serve as a forum for identifying and informing others of those public policies that may impede the ability to deliver the promise of personalized medicine; and
- Create a structure for achieving consensus positions on crucial public policy issues and supporting changes needed to further the public interest in personalized medicine.

In each year since that launch, the PMC has grown: from the 18 charter members to over 120 today. Such expansion is in part because many recognize, even in advance of the plethora of new products that will transform health, that the personalized medicine paradigm represents a significant opportunity to shape the future. In addition, and perhaps more important than the growth in sheer numbers, is the breadth of constituencies represented in the PMC from every sector in health care.

Through a series of seminars and roundtable programs that address the primary barriers to the widespread adoption of personalized medicine, the PMC provides a forum for debating public policy issues surrounding personalized

medicine. In addition, the PMC produces and distributes educational materials to inform policymakers and healthcare leaders about the importance of personalized medicine and its positive evolution.

These materials include:

- *The Case for Personalized Medicine*, a comprehensive review that assesses the state of personalized medicine and the evidence that it will become an integral part of the healthcare system.<sup>1</sup>
- *The Personalized Medicine Landscape*, a research survey commissioned by the PMC that examined the extent to which multiple stakeholders have integrated, or are prepared to integrate, personalized medicine approaches into their research, businesses, and clinical practices.<sup>2</sup>

The PMC also convenes a number of forums for key stakeholders to debate issues surrounding personalized medicine. These events often feature remarks by senior government officials and policymakers. In brief, the PMC believes, as the chart below illustrates, that government plays a critical role in shaping the future of medicine and, indeed, if it is both focused and coordinated, has the power to transform the landscape.

The PMC is also positioned to advise policymakers and regulators by informing and responding specifically to FDA guidance and other government statements on personalized medicine. The PMC’s responses have included, among others:

- *FDA Draft Guidance for Industry, Clinical Laboratories, and FDA staff on In Vitro Diagnostic Multivariate Index Assays (IVDMIA)*: In an August 2007 letter to the FDA, the PMC commented on the clarifications and specific details outlined in the draft guidance and urges the FDA to further revise its outlined policy on reimbursement, timeline, and oversight.<sup>3</sup>
- *Genomics and Personalized Medicine Act of 2007*: The PMC worked with Senator Barack Obama’s staff to shape S.976, The Genomics and Personalized Medicine Act, a bill that aims to improve the coordination of public and private efforts to facilitate the development of safer and more effective drugs, create a biobanking initiative, expand the genomics workforce, and improve the quality of clinical genetic testing.
- *Secretary’s Advisory Committee on Genetics Health and Society (SACGHS)*: In June 2007 the PMC commented on SACGHS’s draft report, *Realizing the Promise of Pharmacogenomics: Opportunities and Challenges*, which examined the potential of pharmacogenomics to advance the development of diagnostics, therapeutics, and prevention strategies to improve health.<sup>4</sup>

In addition, as the United States confronts significant challenges in improving healthcare quality and controlling costs, personalized health care and evidence-based medicine (or comparative effectiveness, as it is sometimes called) are emerging as part of the potential solution. Recent developments in both illustrate the significant ways in which these fields will influence each other and could point the way to patient-centered, evidence-based healthcare solutions. Realizing how critically important it will be to establish policies that promote efficiency while also improving medical outcomes through personalized treatment, the PMC engaged key stakeholders and opinion leaders in personalized medicine and evidence-based medicine in a 2-day event, co-hosted with the Georgetown University School of Nursing &

Health Studies, titled, *21<sup>st</sup> Century Medicine: Personalized and Evidence-Based*. That event brought together over 225 senior academic and industry executives to consider this perplexing and critical dilemma, concluding that reimbursement, regulation, and adoption had to be better aligned than they are at present if we are to realize the seemingly contradictory goals of overall reducing costs while improving care.

## Looking to the Future

Personalized medicine continues to advance at a rapid pace, both scientifically and organizationally, and change is apparent throughout the entire healthcare continuum. Scientific developments include the discovery of specific gene variations associated with multiple sclerosis, heart disease, and HIV, to cite only a few of the almost weekly new discoveries of the genetic origins of health and disease. In response to these advances, medical institutions across the country and globe are now developing centers dedicated to personalized medicine.

Noticing both the scientific advances and the dedication of top medical institutions to personalized medicine,

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policymakers have also begun to introduce specific guidance and legislation addressing developments and potential issues in personalized medicine. The FDA, for example, recently released a recommendation that physicians use a genetic test to determine the correct dosage of warfarin (Coumadin), a blood-thinning drug. In addition, policymakers are also focusing on the ethical and privacy issues that accompany personalized medicine. Congress, for example, is on the verge of enacting the Genetic Information Nondiscrimination Act, a bill that would prohibit employers and insurance providers from denying employment or coverage to anyone based on underlying genetic information.

This increasing focus on personalized medicine in research, medicine, and government is also starting to take hold among

the public. Several companies are starting to offer genetic tests to consumers that can be purchased via the Internet. These new publicly available products are certain to raise consumer consciousness of genetics and health, along with important questions regarding what they mean for patients and society.

As it has in the past, the PMC will help to interpret all these trends, and to channel them into productive directions. Specifically, the PMC will seek to advance the field further by:

- Identifying viable personalized medicine economics and business models
- Advocating the reform of reimbursement policies by drawing on evidence-based case studies of targeted therapies
- Accelerating the adoption of legislation and regulation that support personalized medicine
- Building a personalized medicine-informed healthcare workforce by collaborating with the professional healthcare community

## Conclusion

In his report on personalized health care, Secretary Leavitt outlined the core features of personalized and targeted treatments that would and should characterize medicine in the future. "Personalized health care," he wrote, "means knowing what works, knowing why it works, knowing whom it works for, and applying that knowledge for patients."<sup>5</sup> That bold challenge and the promise contained within it is indeed the goal of the PMC, as well as being the "work of this generation."

## References

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