

Strategic Plan

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

“We can’t win the future with a government of the past.”

**Barack Obama, State of the Union Address,
January 25, 2011**

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Definition

“Personalized medicine refers to the tailoring of medical treatment to the individual characteristics of each patient [in order] 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.”

--President’s Council of Advisors on Science and Technology,
Priorities for Personalized Medicine, 2008

The Role of the Personalized Medicine Coalition

Launched in November 2004 and composed of more than 200 institutions, PMC members see an opportunity to dramatically improve patient care while increasing value in our health care system. Focused exclusively on personalized medicine, the Coalition is a powerful voice in the debate about how to transform health care. PMC brings together every constituency to advance common goals with a well-crafted agenda of research-based policies and educational programs.

Based on the diversity of its membership, the expertise of its staff and its ability to organize the thought leaders in the field, PMC advocates for public policies that will increase investment in and facilitate the adoption of personalized medicine for the benefit of patients and the health system.

In brief, PMC seeks to advance the interests of its members, and more importantly, also create a new economically viable ecosystem for personalized medicine.

Personalized Medicine

At this time of unprecedented scientific and medical advancements, we envision the benefits of health care that is truly personalized, with the capacity to:

- Diagnose a large number of devastating human diseases more accurately.
- Predict individual susceptibility to disease, based on genetic and other factors.
- Detect the onset of disease at the earliest moments, based on newly discovered biological markers and changes at the molecular level.
- Preempt the progression of disease, as a result of early detection.
- Target medicines and dosages more precisely and safely to each patient, on the basis of genetic and other personal factors.
- Increase the efficiency of the health care system by improving quality, accessibility and affordability.

Overcoming Challenges

Achievement of this new era of personalized medicine requires overcoming numerous hurdles.

Regulatory, reimbursement, educational and other barriers, designed for an era of one-size-fits-all, trial and error medicine, can limit product development, undermine public acceptance, and slow adoption of new approaches.

While the value of personalized medicine may be obvious, the pace at which it will transform health care can be accelerated through concerted efforts.

PMC helps bridge the gap between the emerging science and the patient by advocating for public policies that listen to the science, pay attention to the patient, and speed innovation, including through health information technology, to address unmet medical needs while also increasing efficiency in the health system.

Vision

While the potential benefits of personalized 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 science underpinning it and the intervening variables that determine the pace of personalized medicine’s development and adoption are far more complex.

Often, decades-long patterns of intertwined and/or misaligned regulations, guidelines, investment, incentives, and perceptions must be changed.

In contrast to the current era, PMC envisions:

- A dynamic commercial environment for evidence-based, personalized medicine products – supported by clinical practice guidelines and reimbursed to reflect their well-demonstrated value.
- A regulatory system that encourages the development and manufacture of combined diagnostic and pharmaceutical products and stand-alone diagnostics.
- An HHS Office of Personalized Healthcare that directs personalized medicine principles into policies and practice, including comparative effectiveness research.
- A health care delivery system in which health care providers integrate personalized medicine into their practices, have decision-support tools available to support clinical decisions, and can continue to learn about personalized medicine in continuing education programs.
- A patient-provider dialog that understands the need for personalized medicine products and is comfortable with personalized care so that patients receive safe and effective treatments.
- A public and private payment environment that values enhancing patient outcomes through personalized medicine products.

Key Priorities

PMC has three priorities to accelerate the evolution of personalized medicine:

1. Advocate for public policies that will support personalized medicine's continued development through scientific, legislative, regulatory and reimbursement-related efforts.
2. Help build a personalized medicine informed health care workforce by educating providers at the front lines of clinical care about the power of personalized medicine.
3. Form consensus among the major personalized medicine stakeholders to promote the advancement of common goals for a shared vision of medicine's future.

To build a coordinated framework for personalized medicine, PMC will focus its advocacy efforts on:

1. Devising a regulatory framework that accelerates the development of personalized medicine products.
2. Developing flexible and reasonable evidentiary pathways that can underpin reimbursement and regulatory policies more supportive of personalized medicine products.
3. Creating incentives for innovation and adoption of personalized health care products and services throughout the health care system.

Based on its previous experience working on issues such as comparative effectiveness research, co-development of diagnostic and therapeutic products, including laboratory developed tests, PMC is well-positioned to:

- Frame the debate and inform it with supporting data and analyses.
- Balance competing considerations.
- Effect change that creates a new environment for the advancement of personalized medicine.

To realize its goals, PMC will convene forums, issue white papers, sponsor research, and initiate pilot projects on areas such as technology development, reimbursement, and regulatory policy to both accelerate the adoption of personalized medicine approaches and demonstrate their value.

Measures of Success

PMC looks forward to an era when we no longer discuss “personalized medicine” but rather simply medicine. It anticipates new technologies, products, and approaches that prevent illness, save lives, and improve the health care system.

In addition to being an effective proponent for change, to advance its mission, PMC must also:

- Assure that its budget and other resources are sufficiently and clearly aligned to realize its goals
- Forge strategic partnerships
- Build its net assets/reserve fund
- Recruit and retain members



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