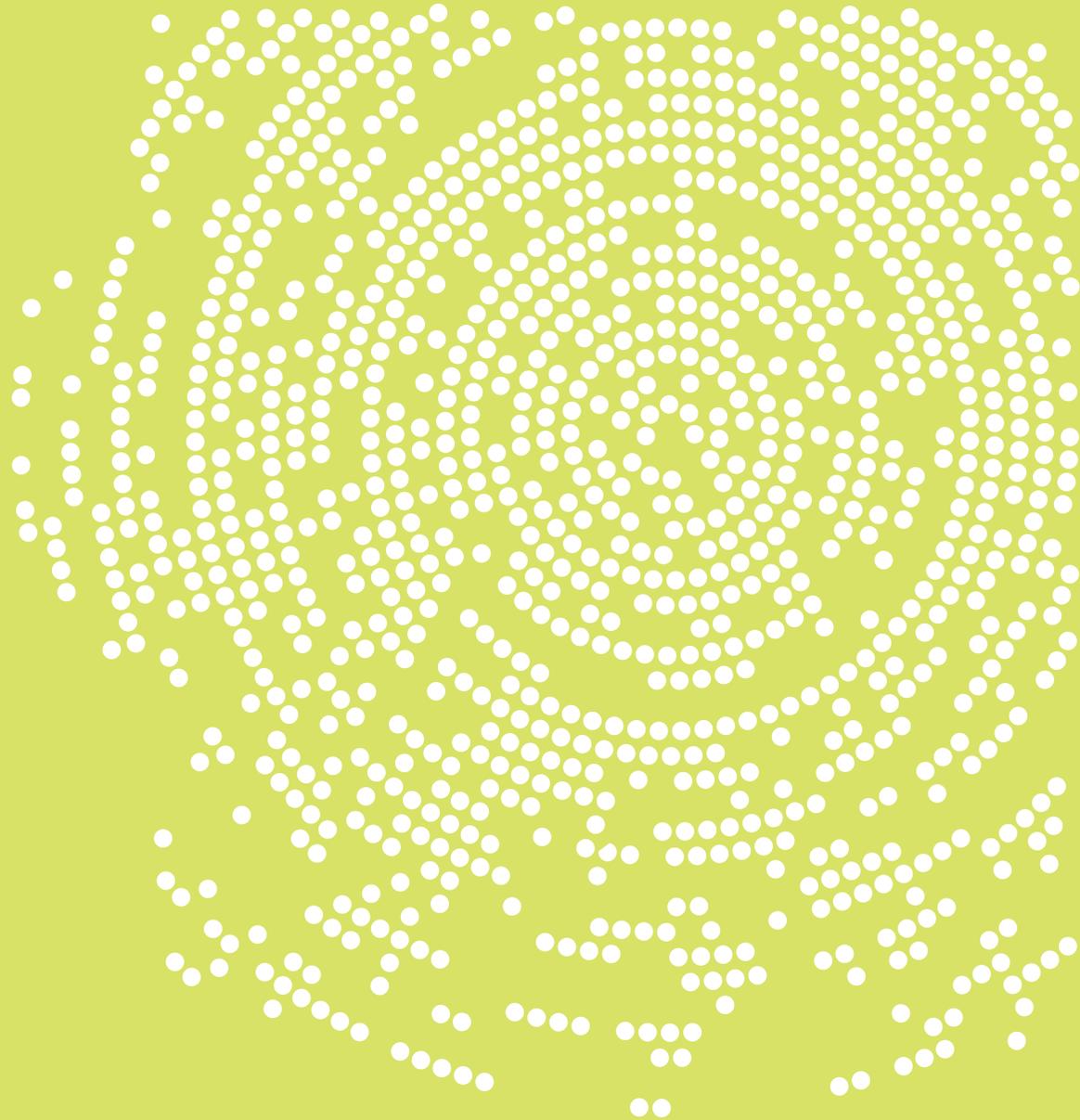




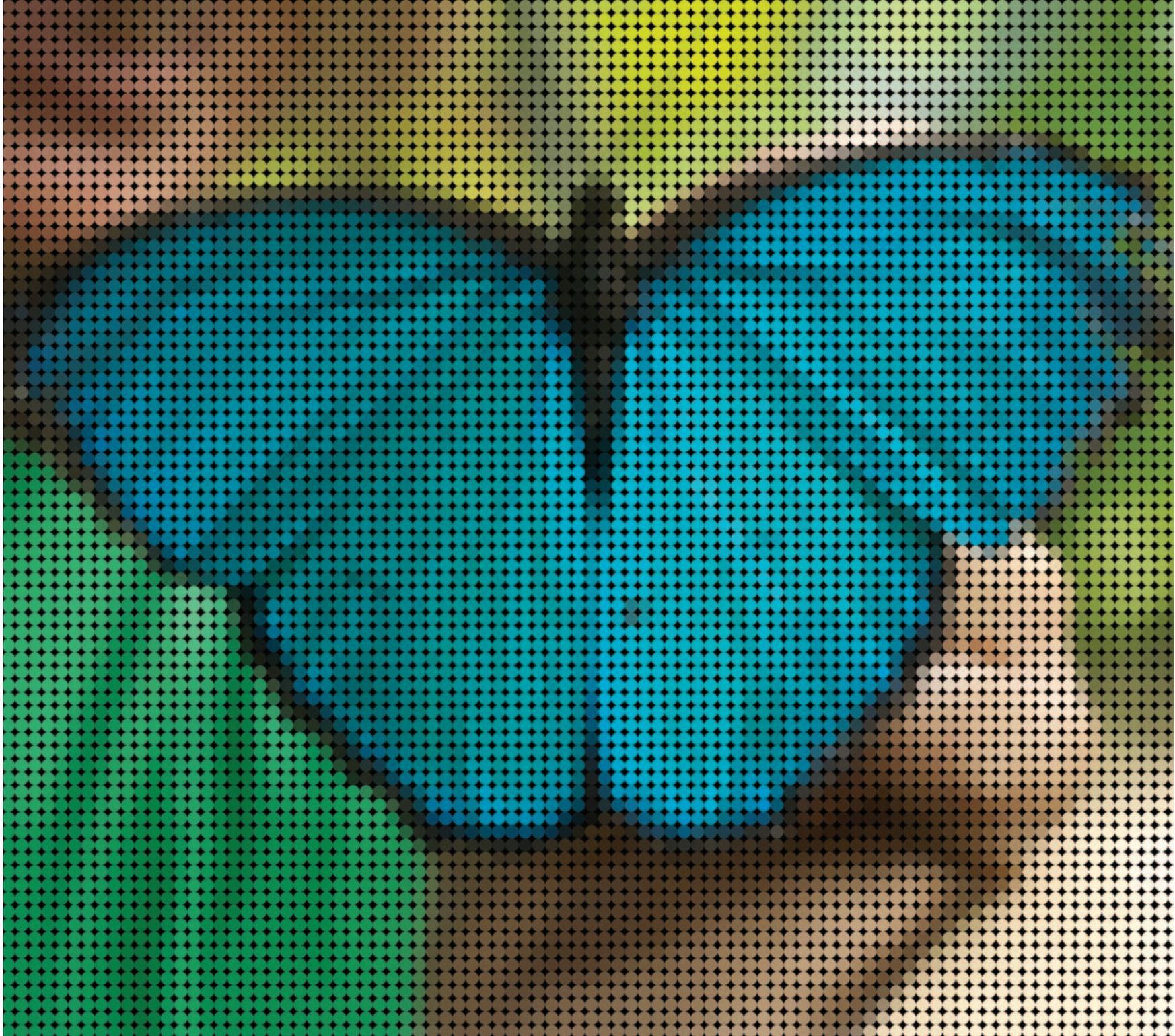
PERSONALIZED MEDICINE COALITION
ANNUAL REPORT 2012

•CHANGEAGENT



The power in tailored therapeutics is for us to say more clearly to payers, providers, and patients—'this drug is not for everyone, but it is for you'—that is exceedingly powerful.

—JOHN C. LECHLEITER, PRESIDENT AND CEO, ELI LILLY AND COMPANY



PARADIGM SHIFT

PERSONALIZED MEDICINE OFFERS A VISION of health care in the 21st century that incorporates new discoveries in biology and the development of new molecular diagnostic tools that can guide therapeutic decisions and move us away from a one-size-fits-all trial and error paradigm into one that is more precise and targeted to groups of patients most likely to benefit.

By increasing efficacy, decreasing side effects including adverse events, and lowering systemic costs, even if the cost of individual products may increase, personalized medicine tailors new medical treatments to patients based on their personal profiles, if not personal values as well. It also represents a paradigm shift in the way we think about medicine.





THE ROLE OF THE PERSONALIZED MEDICINE COALITION

PERSONALIZED MEDICINE

Personalized medicine, according to the President's Council of Advisors on Science and Technology, 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. Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not.

PARADIGM SHIFTS, especially in medicine, do not happen just because the science or new technologies suggest they should. Based on that assumption, at the end of 2004, the Personalized Medicine Coalition (PMC) was launched by some 20 institutions, which spanned the health care ecosystem. They included the pharmaceutical, biotechnology, and diagnostic industries, tool manufacturers, academic health centers, venture capitalists, insurance companies, and patient advocates.

Representing innovators, scientists, providers, payers, and patients, PMC became an international educational and advocacy organization, now numbering over 225 institutions. Along with raising personalized medicine's profile, the Coalition's mission is to advocate for changes that will increase investment in personalized medicine and facilitate its adoption so that both patients and the health system will benefit from improved clinical care and increased overall value.

THE CASE FOR PERSONALIZED MEDICINE

AT THIS TIME OF UNPRECEDENTED scientific breakthroughs and technological advancements, personalized health care has 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 very earliest stages.
- Preempt the progression of disease.
- Target medicines and dosages more precisely and safely to each patient.
- Increase the efficiency of the health care system by improving quality, accessibility, and affordability.

PMC's third edition of its signature publication, *The Case for Personalized Medicine*, issued at the end of 2011, explained how

patients with many different kinds of cancers, for example, are now offered routine molecular diagnoses to improve their chances of survival. Melanoma is no longer just melanoma; it can be characterized by whether it is BRAF positive or negative. Similarly, non-small cell lung cancer can be, for example, EGFR positive or ALK positive, and treated with a drug most likely to improve the patient's health. In fact, scientists are beginning to appreciate the heterogeneity of most diseases, and drug companies are responding by developing more therapeutics for specific subpopulations as well as the processes that lead to drug resistance.

The Case for Personalized Medicine points out that the number of commercially available personalized medicine products has increased from 13 in 2006, when the first edition of document was published, to over 72 today.



The Personalized Medicine Coalition was launched in 2004 by a group of 20 institutions, which spanned the health care ecosystem. Now, PMC's membership roster numbers over

225



OVERCOMING CHALLENGES

MOVEMENT FROM A ONE-SIZE-FITS-ALL, trial and error world to one in which the right patient gets the right treatment at the right time requires overcoming numerous hurdles after the complexities of the science of human biology have been determined. While the benefits of personalized health care are clear—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 more complex. Decades-long patterns of intertwined and/or misaligned regulations, guidelines, investment incentives, and perceptions must be changed to accelerate the development of new personalized medicine products for patients.

PMC believes that these hurdles are many, but three in particular focus our attention: regulation, reimbursement, and education, in part because they are areas of contention.

REGULATION

While the hallmark of personalized medicine is its ability to link diagnostics and drugs, different business models, different development timelines, and especially different regulatory structures define the industries. Within FDA, different centers governed by different rules, regulations, and cultures evaluate drugs and diagnostics. For historic reasons, most molecular diagnostics products enter the market under the authority granted by the Clinical Laboratory Improvement Act of 1988 to the Centers for Medicare and Medicaid Services to oversee laboratories. Large reference clinical laboratories, stand-alone “esoteric” labs which offer specific services, and academic health centers, which develop and conduct many molecular tests, all operate

Personalized medicine tailors new treatments to patients based on their own personal profiles and personal values.



in this system, a system that stimulates the development of a great many diagnostic tests, even if it is not one that encourages co-development of highly-regulated drugs with diagnostics.

FDA has recognized this challenge. Recently, it approved two new co-developed targeted therapeutics and diagnostics together in record time as well as other groundbreaking targeted therapeutics this year. It is expected to issue draft guidance documents to help clarify the field so that more are developed in the future.

Congress is also considering a number of competing solutions to address questions regarding the regulation of laboratory developed tests (LDTs). PMC, believing that what is required is a clear and transparent regulatory system flexible enough to accommodate our rapidly growing understanding of individual variation believes that Congress should incentivize investment in co-developed products by enacting R&D tax credits, streamlining review, and ensuring Medicare coverage.

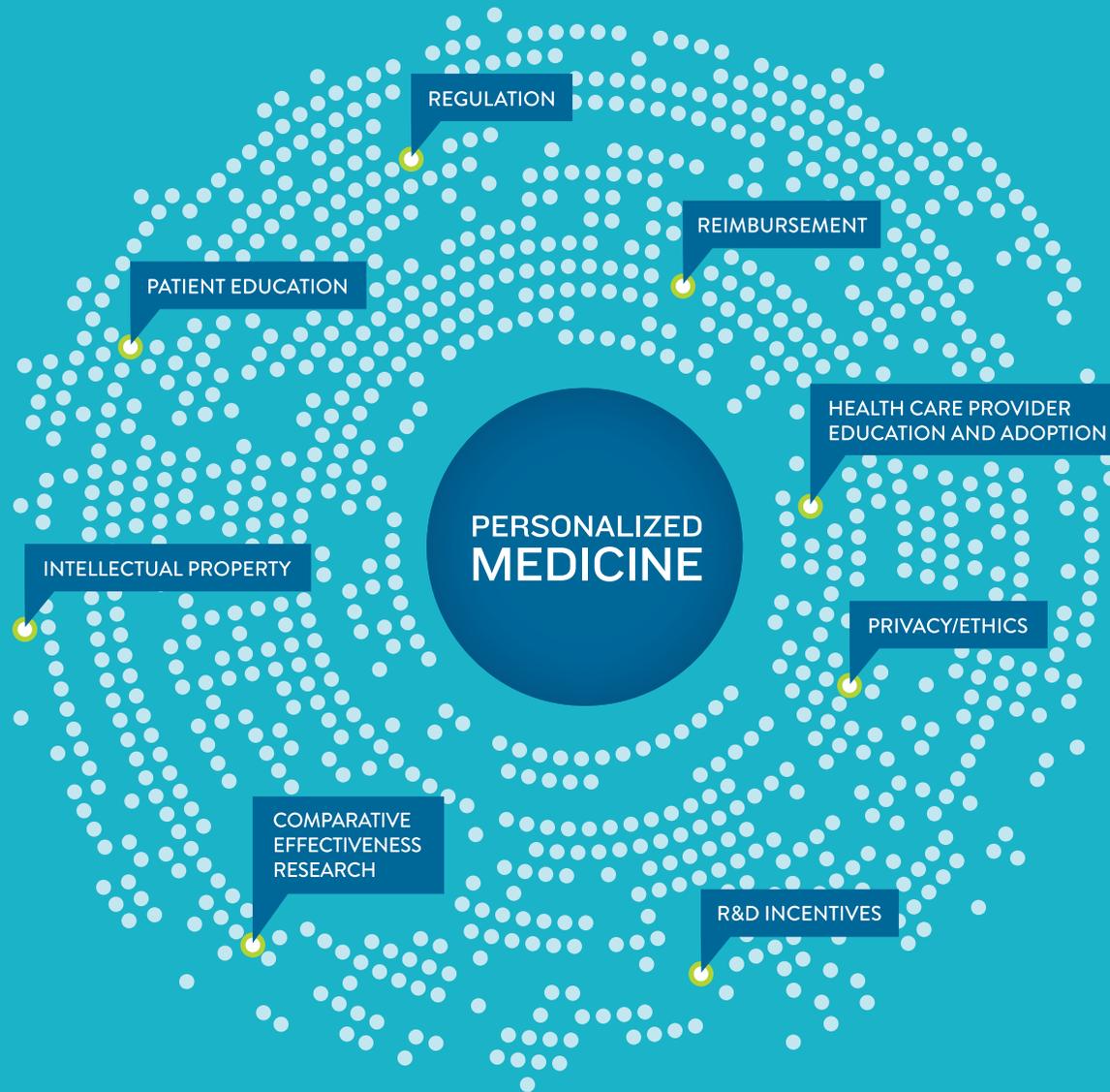
Meanwhile, as science and technology progress, the need to update our regulatory systems to accommodate these developments becomes more acute. The emergence of complex genetic testing, including whole genome sequencing, will further challenge a regulatory structure not designed to facilitate the development of personalized medicine, limiting access to new discoveries and treatments for serious diseases. Representing the patient point of view, PMC continues to engage the diagnostic, pharmaceutical, and payer

communities in a dialog about how they can join forces to support the medicine of the future.

COVERAGE, CODING AND PAYMENT

Regulatory approval of personalized medicine products and services is necessary but not sufficient. Coverage and payment are also needed to encourage investment in new molecular diagnostics. While public and private insurers recognize the benefit of molecular testing in patient management,

ISSUES IMPACTING PERSONALIZED MEDICINE



payers rightly require evidence of its clinical, if not economic, value; though they have been slow to define what levels of evidence they consider adequate.

An open and critical issue is what kinds of evidence should determine coverage and payment decisions for products whose cost cannot justify a controlled randomized clinical trial or for changes like the introduction of new biomarkers that improve the product. Moreover, if diagnostic tests are not reimbursed, evidence of their utility cannot be developed, creating a classic “Catch 22” situation. Combined with CMS’s tendency to pay for innovative molecular tests based on materials and performance steps, rather than on their development costs (including clinical trials), complexity, or the difficulty in interpreting them, another hurdle has been added to the mix. In addition, with some notable exceptions, CMS rules for Medicare preclude payment

for screening tests that predict and prevent disease before it occurs, a large part of the promise of personalized medicine.

To address these issues, and in concert with the payer community, PMC is focusing more attention on the evidentiary standards and data requirements for payer coverage and what incentives may be necessary to encourage development of personalized medicine diagnostic products. We will examine in particular the challenges that large scale randomized clinical trials pose for developing diagnostics, while also exploring alternative models for meeting evidentiary standards for multiple purposes.

EDUCATION

Physicians and other health care providers, it has been noted, sometimes are slow to change practice absent of conclusive evidence that the proposed change, notably one that requires a new

procedure or test, will produce a better result. It is not enough that new products are brought to market. They must be adopted if patients are going to benefit.

A recent survey by the American Medical Association and a pharmacy benefit manager found that 98 percent of physicians are aware that patient genetic profiles influence therapy, but only 10 percent believe that they have the knowledge to use genetic information in practice. Combined with the inherent conservatism of many medical societies, that lack of understanding limits the pace of change and slows the improvement of clinical care. PMC believes that we need to build a personalized medicine informed health care workforce by educating providers at the front lines of clinical care about the power of personalized medicine, and will examine the best ways to incorporate personalized medicine concepts and products into the practice of medicine.

LOOKING FORWARD

As we wrote in *The Case for Personalized Medicine*, “The long arc of medical history has been one in which diagnostic capability has evolved from the metaphysical, to the anatomical, to the cellular, and ultimately to the molecular level. Now that a number of diseases can be sub-classified using evidence well beyond what is visibly obvious into categories that presage the course of disease and its likely response to treatment, there is an obligation to act on that information.”

We understand that the case is far from closed and that we need more evidence to support our contentions, notably personalized medicine’s ability to increase health care quality while lowering overall systemic costs. But this is the opportunity that our generation has been given. To make it a reality is going to require the combined resources of multiple stakeholders—all willing to invest in a paradigm change that can preserve innovation, improve outcomes, and reduce the overall costs of health care.

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(LabCorp)
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Onyx Pharmaceuticals
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American Clinical Laboratory
Association
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PhRMA

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Merck
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Novartis
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PATIENT ADVOCACY GROUPS

Accelerated Cure Project for
Multiple Sclerosis
Adriana Jenkins Foundation for
Personalized Medicine
Alliance for Aging Research
American Liver Foundation
Cancer Commons
Carcinoid—NeuroEndocrine
Tumour Society—Canada
Genomix Canada
Go Health America
International Cancer Advocacy
Network (“ICAN”)
Melanoma Research Alliance
Foundation (MRA)
Multiple Myeloma Research
Foundation

National Alliance for
Hispanic Health
National Brain Tumor Society
National Patient Advocate
Foundation

PERSONALIZED MEDICINE SERVICE PROVIDERS

23andMe
Cureline, Inc.
Genophen, Inc.
Institute for Personalized Medicine
Intervention Insights
iSpecimen Inc.
Michael J. Bauer, MD &
Associates, Inc.
Pathway Genomics Corporation
Precision Health

RESEARCH, EDUCATION, & CLINICAL CARE INSTITUTIONS

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Cancer Research
American Institute for Medical &
Biological Engineering (AIMBE)
American Medical Association
American Society of Human
Genetics (ASHG)
Association for Molecular
Pathology (AMP)
Atlantic Health System
Australian Institute for
Bioengineering and Nanotechnology
Baylor Health Care System
Precision Medicine Institute
Brown University

Catholic Health Initiative's
Center for Translational Research
Cepmed
Children's Hospital & Research
Center Oakland
Cleveland Clinic
College of American Pathologists
Coriell Institute for Medical Research
CREATE Health Translational
Cancer Centre, Lund University
The Critical Path Institute (C-Path)
Decatur Memorial Hospital
Duke University
El Camino Hospital
Essentia Institute of Rural Health
Fairbanks Institute for Healthy
Communities
Fairleigh Dickinson University
School of Pharmacy
FasterCures
Genome British Columbia
Genome Canada
The George Washington University
Medical Center
H. Lee Moffitt Cancer Center &
Research Institute
Indiana Institute of Personalized
Medicine
Inova Health System
Institute for Systems Biology
Institute for Translational Oncology
Research (ITOR)
Instituto Cartuja Hospital Molecular
International Society of
Personalized Medicine

The Jackson Laboratory
The Dr. John T. Macdonald
Foundation Department of Human
Genetics, University of Miami
Knight Cancer Institute-Oregon
Health & Sciences University
Marshfield Clinic
Mayo Clinic
National Foundation for
Cancer Research
National Jewish Health
National Pharmaceutical Council
NorthShore University HealthSystem
The Ohio State University
Medical Center
Partners HealthCare Center for
Personalized Genetic Medicine
Poliambulatorio Euganea Medica
Raabe College of Pharmacy,
Ohio Northern University
RTI International
Stanford University School
of Medicine
United States Diagnostic Standards
(USDS)
University of Florida
University of Kansas
University of Maryland School
of Medicine
University of Pittsburgh Medical
Center (UPMC)
University of Rochester
University of South Florida Morsani
College of Medicine
University of Utah

Vanderbilt University Medical Center
VCU Health System

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Cynvenio Biosystems, Inc.
DNA Genotek Inc.
Genia Technologies
Illumina, Inc.
Life Technologies Corporation

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ab+c
Archon Genomics X PRIZE
Beaufort, LLC
Bionest Partners
Bioscience Valuation BSV GmbH
Boston Healthcare
CAHG
Cambridge Healthtech Institute
Clark & Elbing LLP
ConText
CryerHealth
Defined Health
The Dohmen Company
EdgeTech Law LLP
Ernst & Young Global Life
Sciences Center
Feinstein Kean Healthcare
Foley & Lardner LLP
Genomic Healthcare Strategies
GfK Bridgehead
Hanson Wade
Health Advances, LLC
HealthFutures, LLC
Hogan Lovells LLP

Jones Public Affairs
Kilpatrick Townsend & Stockton LLP
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Manning & Napier Advisors, LLC
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ML Strategies, LLC
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Pendergast Consulting
Personalized Medicine in Oncology™
Personalized Medicine Partners, LLC
Personalized Medicine World
Conference
PricewaterhouseCoopers LLP
Russell Reynolds Associates
Sanford Rose Associates—San Diego
Scientia Advisors
Slope Partners
Spectrum
Wilson Sonsini Goodrich & Rosati

VENTURE CAPITAL

Burrill & Company
Kleiner Perkins Caufield & Byers
Mohr Davidow
Pappas Ventures
Third Rock Ventures, LLC

FINANCIAL OVERVIEW

PMC CONTINUED TO HAVE A VERY STRONG financial position in 2011. Revenues increased by 5 percent as a result of an expanded membership database. As a result, PMC ended the year with \$321,000 of net surplus, which increased its reserves to nine months of expenditures compared to six months in 2010 (average in the industry for an organization of this size is six months). Net assets ratio remained strong as well at a healthy 78% compared to 72% in 2010 (average for similar nonprofits is 60%).

The financial results are derived from the PMC's audited December 31, 2011 financial statements, which contain an unqualified audit opinion. PMC's complete audited financial statements can be obtained at pmc@personalizedmedicinecoalition.org or by calling 202.589.1770.

STATEMENT OF ACTIVITIES

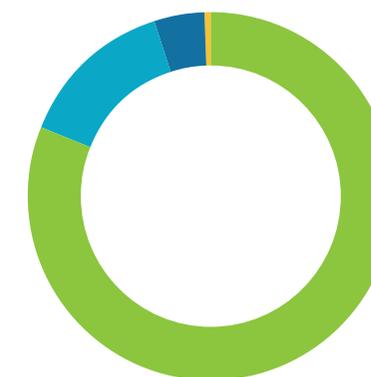
REVENUES	AMOUNT
Membership dues	\$1,307,670
Sponsorship	204,500
Support for PMC Policy	20,000
Membership events	45,000
Admission fees	26,389
Interest income	1,440
Miscellaneous income	6,433
TOTAL REVENUES	\$1,611,432
EXPENDITURES	
General & administrative	944,601
Professional fees	142,391
Education	102,764
Business development	100,033
TOTAL EXPENDITURES	\$ 1,289,789
CHANGE IN NET ASSETS	\$ 321,643

STATEMENT OF FINANCIAL POSITION

ASSETS	AMOUNT
Cash & cash equivalents	\$1,165,075
Accounts receivable	19,383
Prepays, deposits, & other assets	72,526
Property & equipment, net	6,263
TOTAL ASSETS	\$1,263,247
LIABILITIES	
Accounts payable & accrued expenses	19,604
Deferred revenue	252,250
TOTAL LIABILITIES	\$ 271,854
NET ASSETS	
Unrestricted net assets	991,393
TOTAL NET ASSETS	\$ 991,393

2011 REVENUES

	% TOTAL
Membership dues	81.15%
Sponsorship & support	13.93%
Events & fees	4.43%
Interest & miscellaneous	0.49%



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.



PERSONALIZED
MEDICINE COALITION

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