

EDUCATION
ADVOCACY
IMPACT

The Personalized Medicine Coalition
2015 Annual Report



“[Personalized medicine] gives us one of the greatest opportunities for new medical breakthroughs that we have ever seen.”

– President Barack Obama

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Dear Colleague:

When, in his State of the Union Address, President Obama called for a “Precision Medicine Initiative” that would, he said at a White House ceremony 10 days later, unleash “one of the greatest opportunities for new medical breakthroughs that we have ever seen,” he underscored PMC’s ongoing contention that a new era in medicine is within our reach. If we invest wisely in research and put in place new and carefully calibrated systems to ensure that government keeps pace with emerging science and technology, we can, he noted, improve both patient care and the efficiency of the health care system.

But the President also recognized a second reality, which is that this paradigm shift will not happen just because the science and new technologies suggest it should. This is the reality on which the Coalition has built its portfolio of activities.

The President’s program has four parts, which include: increased funds for the National Cancer Institute to study the genetic factors that cause cancer; the creation of a “voluntary national research cohort” of one million Americans who would share genomic data, lifestyle information, electronic health records and biological information in order to answer questions about wellness and disease; additional funds for the Food and Drug Administration to update its ability to regulate personalized medicine technologies; and, not least, more financial support for the Office of the National Coordinator to develop interoperability standards to secure the exchange of health data across systems.

In brief, the President has recognized, as PMC has contended since it was publicly launched in 2004, that a move from one-size-fits-all/trial-and-error medicine to health care based on an understanding of individual variation necessitates systems-level change. In addition to further understanding the biological basis of patient heterogeneity, it requires a willingness to reconsider and reform the intervening variables impacting the delivery of new treatments to patients, which include regulation, reimbursement and education. Through these efforts, we can provide better health care solutions, including enhanced abilities to predict and prevent disease, personalize treatments, and develop a more value-oriented health system.

PMC had tremendous success promoting this agenda in 2015. Having organized all of the stakeholders around the world with an interest in advancing personalized medicine, the Coalition’s voice is sought out and respected — by government as well as health care manufacturers and providers, which, like government, are required to alter their systems to keep up with changing science and technology.

Like PMC itself, this report is focused on three themes: education, advocacy and impact.

We invite you to read it and share with us your thoughts as we move into the second decade of promoting personalized medicine so that both patients and our health system benefit from improved clinical care and increased overall value.

We believe that this is the future of medicine, and are committed to getting us there.

Sincerely yours,

Edward Abrahams, Ph.D.
President

William Dalton, Ph.D., M.D.
Chair of the Board

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient. By combining the data from those tests with an individual's medical history, circumstances and values, health care providers can develop targeted treatment and prevention plans.

– PMC's definition of personalized medicine

EDUCATION

Educating stakeholders is of paramount importance to personalized medicine's success. A 2014 survey by the Coalition revealed that 62 percent of Americans have never heard of personalized medicine, and data from the communications firm CAHG suggests that only 20 percent of physicians have any training in how to administer it. In 2015, PMC acted to define the field, uncover the challenges and outline solutions for stakeholders throughout the health care system.

Defining the Field

The 11th Annual State of Personalized Medicine Luncheon Address

Like previous iterations of the event, this year's State of Personalized Medicine Address served as a forum at which PMC members and guests from across the health care community engaged policy leaders in a discussion of the key issues facing the field, solidifying PMC's role as, in Pfizer Chairman of the Board and CEO Ian Read's words during this year's event, "the one place where innovators, scientists, patients, providers and payers all come together to collaborate, debate and educate the public and the private sectors."

Following an introduction from Read, this year's address was delivered by the Honorable Michael C. Burgess, M.D. (R-TX), a member of the U.S.

House of Representatives Subcommittee on Health, just hours after the subcommittee's mark-up of the *21st Century Cures* draft bill on May 14.

Burgess identified and analyzed several of the most pressing policy issues in the field. He drew the audience's attention in particular to the interoperability provisions in the *Cures* bill, which align with concepts in President Obama's Precision Medicine Initiative, and presented himself as an advocate for innovation in laboratory-developed testing and a champion of participatory research.

Nearly 200 personalized medicine stakeholders attended the event, which took place at the National Press Club in Washington, D.C.

Personalized Medicine: Improving Patient Care in the 21st Century

As the U.S. Senate began to examine its priorities in personalized medicine following the passage of the *21st Century Cures Act* by the U.S. House of Representatives Energy and Commerce Committee, the Honorable Amy Klobuchar (D-MN) recognized a need to educate her colleagues in the Senate.

The Coalition responded by organizing a Hill briefing titled *Personalized Medicine: Improving Patient Care in the 21st Century*, which convened more than 125 individuals, including more than 50 Congressional staffers, in the Kennedy Caucus Room of the Russell Senate Office Building on July 16. The briefing was co-hosted by Senators Klobuchar and Orrin Hatch (R-UT).

Designed to provide an overview of what personalized medicine is and why it is important, the event featured introductory remarks from Klobuchar and Stephanie Haney, a stage IV lung cancer patient, as well as comments from a panel of experts from among PMC's membership. Keith Stewart, M.B., Ch.B., director of Mayo Clinic's Center for Individualized Medicine, Greg Keenan, M.D., vice president of medical affairs and U.S. head medical officer at AstraZeneca, and Michael Pellini, M.D., CEO of Foundation Medicine, joined Kathy Hudson, Ph.D., deputy director for science, outreach and policy at the National Institutes of Health (NIH), on a panel that explored how the field is progressing in an era of constrained resources.

Personalized Medicine's Benefits

PMC presented Congressional staffers with statistics on personalized medicine's potential in July.

PERSONALIZED MEDICINE IMPROVES HEALTH OUTCOMES

Myelogenous Leukemia 5-year Survival Rate

Following introduction of imatinib, a targeted therapy



2X

Colorectal Cancer 5-year Survival Rate

Following discovery of molecular receptors associated with tumor growth



15%

Heart Patient Hospitalization Rate

Documented when genetic information was used in dosing warfarin



30%

PERSONALIZED MEDICINE CAN MAKE THE HEALTH SYSTEM MORE EFFICIENT

Chemotherapy Use

If women with breast cancer received genetic testing prior to treatment

34%



Colorectal Cancer Costs

If metastatic colorectal cancer patients received genetic testing prior to treatment

\$604M



Strokes Prevented

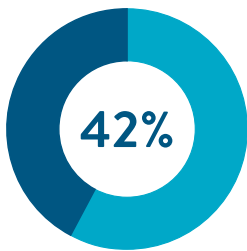
If a genetic test was used to properly dose blood thinners

17K

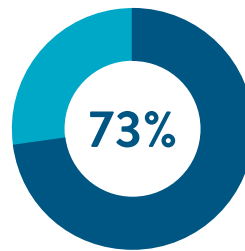


A New Landscape for the Pharmaceutical Industry

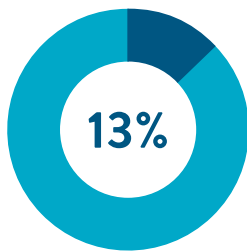
PMC research illustrates the biopharmaceutical industry's deep commitment to personalized medicine.



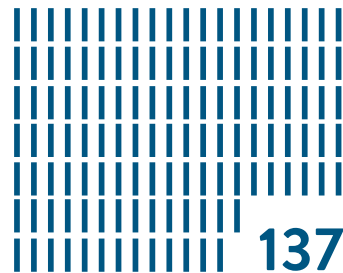
of all drugs in development are personalized medicines.



of oncology drugs in development are personalized medicines.



Personalized medicines represent 13% of all approved medicines.



approved medicines have genomic information in their label.

Uncovering the Challenges

PMC Report: Industry is Investing in Personalized Medicine Despite Obstacles in Science, Regulation and Reimbursement

An article on the promise of personalized medicine published in the *Harvard Business Review* in 2007 identified the pharmaceutical industry's reluctance to abandon the "blockbuster" drug development model, which favors the development of drugs for as broad a patient group as possible, as a barrier to the advancement of the field. With its finger on the pulse of the industry, PMC recently decided to test that widely accepted contention, collaborating with the Tufts Center for Drug Development to document the level of commitment to personalized

medicine on the part of the pharmaceutical and diagnostics industries.

The findings, which were released in May of this year, demonstrate that although the industry is increasing its investment in targeted therapies, challenges in science, regulation and reimbursement still concern executives.

"Companies are confounded when regulatory and payment policies do not support targeted therapies," PMC Executive Vice President Amy M. Miller, Ph.D., told *GenomeWeb*. "The science is so hard and the benefit to patients so striking that the rest should naturally follow, in the eyes of the developers."

"Companies are confounded when regulatory and payment policies do not support targeted therapies. The science is so hard and the benefit to patients so striking that the rest should naturally follow, in the eyes of the developers."

— PMC Executive Vice President Amy M. Miller, Ph.D., in *GenomeWeb*, May 20, 2015

Outlining the Solutions

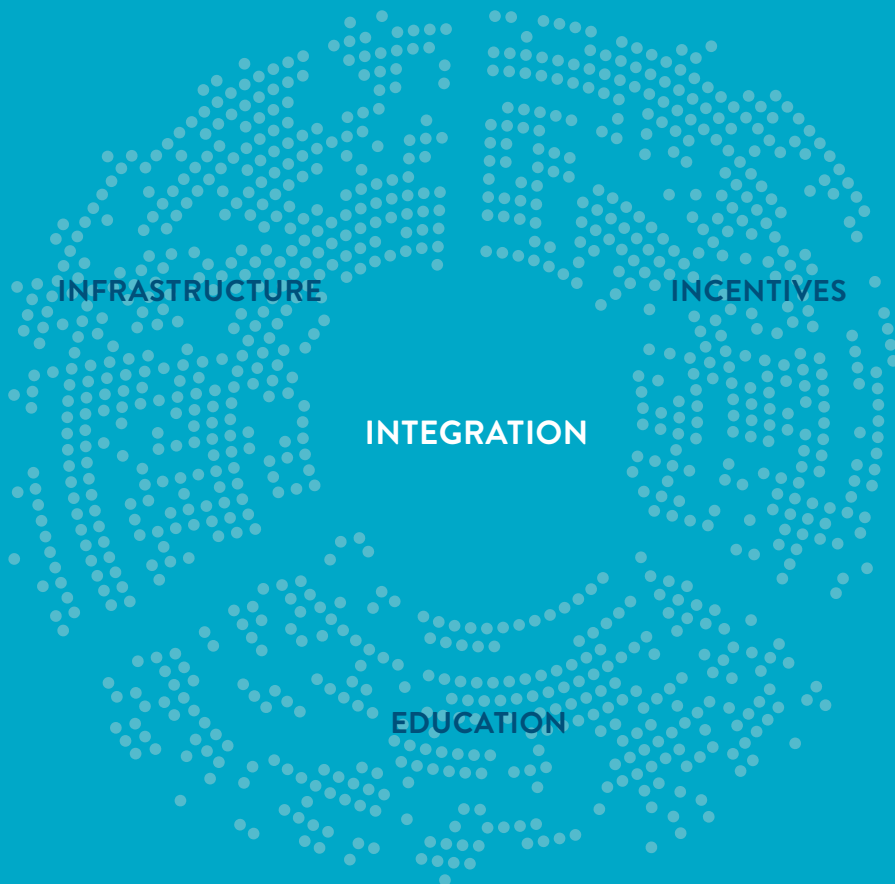
Integrating Personalized Medicine into Health Care: The 2nd PMC/BIO Solutions Summit

Through conversations with members in the provider community, PMC has recognized the need to determine the best practices to integrate personalized medicine into clinical care. In October, the Coalition co-hosted the 2nd PMC/BIO Solutions Summit, *Integrating Personalized Medicine into Health Care*, to organize the community's thinking on this topic.

Convened by PMC and the Biotechnology Industry Organization (BIO), the conference demonstrated how the right combination of education initiatives, state-of-the-art infrastructure and appropriate incentives can facilitate the adoption of personalized approaches to clinical care. The discussion suggested that education efforts should focus in particular on the value of personalized medicine; infrastructure should allow for the management of large amounts of data; and incentives should reward improved outcomes.

Principles for Integrating Personalized Medicine Into Health Care

The PMC/BIO Solutions Summit demonstrated that integrating personalized medicine into a health care system requires initiatives to educate providers, policymakers and patients; state-of-the-art IT and program operations infrastructure; and incentives to use personalized clinical approaches to care.



“Personalized medicine is transforming the practice of medicine, and the Personalized Medicine Coalition is playing a critical role in bringing together all of the stakeholders to help make that happen.”

– Raju Kucherlapati, Ph.D., Paul C. Cabot Professor of Genetics, Harvard Medical School

ADVOCACY

Guided by the recognition among its members that science, regulation and reimbursement are the key challenges facing personalized medicine, PMC continued to champion policies to incentivize innovation, modernize regulation and rethink reimbursement in 2015.

Incentivizing Innovation

Comment Letter on the U.S. Senate HELP Committee's Innovation for Healthier Americans Initiative

When the U.S. Senate Health, Education, Labor & Pensions (HELP) Committee solicited comments in its *Innovation for Healthier Americans* white paper, which was released in January, PMC urged the committee to ensure that personalized medicine is considered as the initiative moves forward.

“Our interest in the *Healthier Americans* initiative pertains to how personalized medicine can benefit the health care system by improving the quality, safety, accuracy and effectiveness of treatments,” PMC’s comment letter to the committee reads. “Furthermore, health care

system spending can be reduced as considerable resources spent on ineffective treatments for a particular patient as well as the associated costs for visits to the doctor and hospital are avoided.”

In its comment letter, which was submitted in February, PMC advocated for policies that:

1. Incentivize the development of new, personalized approaches to care
2. Establish a predictable and flexible regulatory system that is responsive to new scientific discoveries
3. Encourage health care innovations through proactive coverage and payment systems.

Modernizing Regulation

Comment Letter on FDA’s Framework for Laboratory-Developed Test Regulation

Following FDA’s release of a proposed framework for regulating laboratory-developed tests (LDTs) in July of 2014, PMC convened a working group of members to discuss strategies to ensure that the framework would not have an adverse impact on the development of innovative LDTs that contribute to personalized medicine’s advancement. The group’s work product was finalized and submitted to FDA as a comment letter in February.

The letter recommends that FDA refine its proposal, publish a new draft of the framework and collect additional feedback from the public prior to implementation. Specifically, the letter indicates that an updated draft should include:

- Additional details on how FDA will classify different types of LDTs
- Clarification on how FDA’s new regulatory practices harmonize with regulations already in place at the Centers for Medicare & Medicaid Services (CMS)

“It is clear that, at the very least, a second draft of the framework should be issued together with draft guidance documents clarifying the missing pieces for the review and public engagement process to be complete,” the letter reads.

Comment Letter on FDA’s Consideration of the Oversight of Next-Generation Sequencing

In December of 2014, FDA began exploring an initiative that would dramatically alter the landscape for personalized medicine regulation – the oversight of next-generation sequencing technologies. PMC worked with its members to draft a comment letter in response to FDA’s preliminary paper on the topic, which was sent to the agency in March. The letter urges FDA to be thoughtful in approaching the topic.

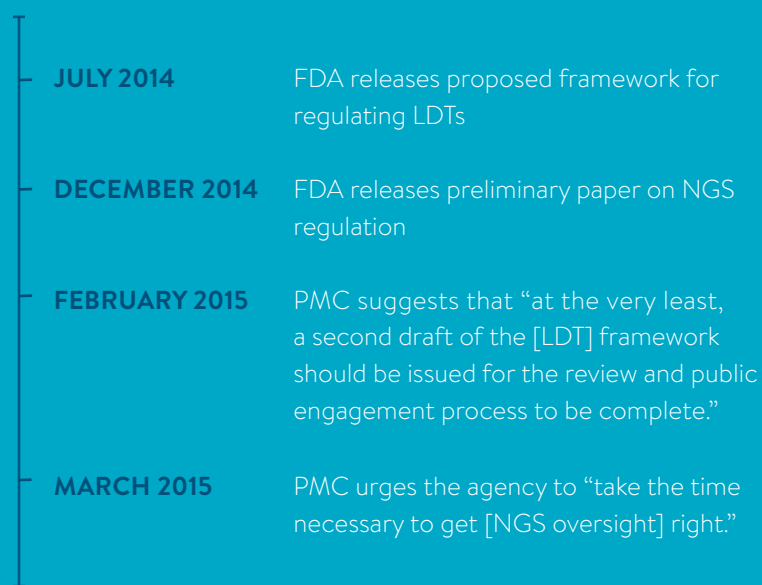
“We urge the agency to take the time necessary to get [next-generation sequencing oversight] right,” the letter reads. “Future investment in the field depends on clear, reasonable guidelines, which are in our power to develop now.”

The letter also outlines three key principles for FDA to consider as it moves the initiative forward, reminding the agency that:

- Next-generation sequencing information must be accurate and reliable
- Patients should be assured optimal access to these state-of-the-art technologies
- It is important to continue to work with all stakeholders to develop important details on how such an oversight system would be resourced, standardized and administered.

The Need for a Thoughtful Approach

In comment letters this year, PMC encouraged FDA to be thoughtful in its approach to regulating laboratory-developed tests (LDTs) and next-generation sequencing (NGS).

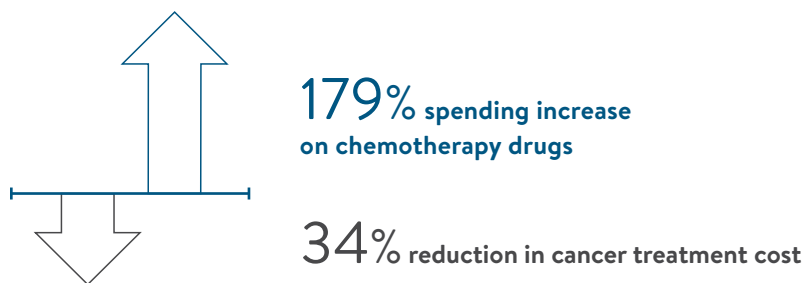


JULY 2014	FDA releases proposed framework for regulating LDTs
DECEMBER 2014	FDA releases preliminary paper on NGS regulation
FEBRUARY 2015	PMC suggests that “at the very least, a second draft of the [LDT] framework should be issued for the review and public engagement process to be complete.”
MARCH 2015	PMC urges the agency to “take the time necessary to get [NGS oversight] right.”

Challenging Assumptions

The Coalition's 2015 white paper highlighted the results of a UnitedHealthcare pilot study suggesting that increased spending on drugs does not necessarily lead to an increase in total costs — in fact, the opposite may be true.

AFTER THREE YEARS



Approximately **\$40,000 was saved per chemotherapy patient** despite spending more on chemotherapy drugs

Rethinking Reimbursement

Paying for Personalized Medicine: How Alternative Payment Models Could Help or Hinder the Field

Following the U.S. Department of Health and Human Services' announcement that it plans to tie 50 percent of traditional, fee-for-service Medicare payments to alternative payment models (APMs) by 2018, PMC drew attention to how APMs could impact personalized medicine in its white paper titled *Paying for Personalized Medicine: How Alternative Payment Models Could Help or Hinder the Field*. The paper reminds stakeholders that depending on how they are structured, APMs could accelerate or stifle personalized medicine's progress.

"Understanding each type of APM, and how it affects both the utilization and development of innovative treatments for complex diseases, is key to understanding the implications of APMs for personalized medicine," the paper reads.

Through an exploration of accountable care organizations (ACOs), "bundled payments" and medical homes, the paper uncovers factors that

are essential to the future development of APMs. These factors include:

- The degree of transparency in the development of APMs
- The role of informed decision-making based on research in genomics and other areas
- The use and appropriate weighting of clinical quality measures that are focused on outcomes
- The structure of provider financial incentives that support patient choice
- The inclusion of mechanisms to recognize and encourage appropriate adoption of personalized medicines

The Centers for Medicare & Medicaid Services (CMS) Acting Administrator Andy Slavitt responded to the Coalition's concerns about the structure of APMs in June, indicating in a letter to PMC that CMS plans to put policies in place that protect the use of "new, breakthrough technologies."

“[PMC is] the one place where innovators, scientists, patients, providers and payers all come together to collaborate, debate and educate the public and private sector.”

— Ian C. Read, Chairman of the Board and CEO, Pfizer

IMPACT

The Coalition’s impact was evidenced by these opening remarks from the Honorable Fred Upton at a Subcommittee on Health hearing last year, in which the Congressman cited content from the Coalition’s website:

“According to the Personalized Medicine Coalition, ‘While the potential benefits of personalized [medicine] 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.’”

Getting Noticed

Spotlighting the Field

Through its education and advocacy efforts, the Coalition has earned a place among the most influential organizations in personalized medicine policy. In addition to having its online content cited last year during the Subcommittee on Health hearing referenced above, PMC President Edward Abrahams, Ph.D., participated in a roundtable discussion on personalized medicine with members of the U.S. House Energy and Commerce Committee during

the committee’s effort to develop the *21st Century Cures Act* that was passed by the House in 2015. The Coalition is routinely consulted for comments on personalized medicine issues, and has been featured in more than 40 news stories about personalized medicine in 2015 alone.

But far more importantly, PMC augments and provides a showcase for the ongoing work of its more than 250 member institutions, which are advancing the personalized medicine paradigm despite extraordinary obstacles.

Measuring Progress

PMC Analyses Demonstrate Targeted Therapies Are Finding Favor at FDA

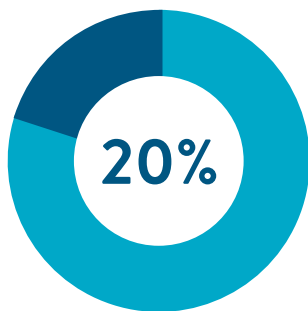
Eager to showcase its commitment to the field, FDA requested that PMC conduct an analysis in January of 2015 to highlight the percentage of the agency's 2014 approvals that are personalized medicines. The results of this effort were extraordinary.

PMC's analysis revealed that nine of FDA's novel new drug approvals in 2014 are personalized medicines, which represents 20 percent

of the total. The analysis supports former FDA Commissioner Margaret Hamburg's claim, issued when she resigned, that FDA had "ushered in the era of personalized medicine" under her direction.

PMC followed its examination of 2014 drug approvals with another analysis in July, recognizing FDA's record-breaking month for personalized medicine approvals, during which it approved four indications for personalized medicines.

"Ethically and scientifically, there is no going back," PMC proclaimed.



of FDA's 2014 Novel New Drug Approvals Were Personalized Medicines

Indications Include:

1. Lynparza (olaparib)
2. Vimizim (elosulfase alfa)
3. Cyramza (ramucirumab)
4. Zykadia (ceritinib)
5. Beleodaq (belinostat)
6. Cerdelga (eliglustat)
7. Harvoni (ledipasvir and sofosbuvir)
8. Viekira Pak (ombitasvir, paritaprevir and ritonavir; dasabuvir)
9. Blinicyto (blinatumomab)

TOWARD A NEW ERA

As demonstrated by this report and by PMC's activities, a new landscape for personalized medicine is emerging. With continued support for the education and advocacy efforts underpinning this progress, so too will a new era in health care. Reaching this goal, however, will require the combined resources of multiple stakeholders, including government — all willing to invest in innovation, improved outcomes and the reduction of systemic health care costs.

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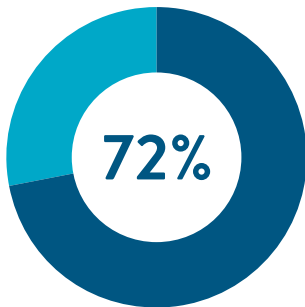
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 Third Rock Ventures, LLC

FINANCIAL OVERVIEW

PMC coupled additional revenues from members and sponsors with an effective financial management strategy to grow its program portfolio in 2014, and has developed an expanded list of potential sponsorship opportunities to support continued progress in coming years. The Coalition's staff is directly responsible for implementing PMC's programs, with 72 percent of its total expenses supporting the Coalition's programming. Revenues were increased by 10 percent in 2014, and PMC finished the year with seven months' of expenditures in reserve. The ratio of current assets (\$1.5 million) to current liabilities (\$368 K) is 4.21 to 1, up from 3.72 to 1 last year.

The financial results are derived from PMC's IRS form 990 and audited December 31, 2014 financial statements, which contain an unqualified audit opinion. These documents can be obtained at pmc@personalizedmedicinecoalition.org or by calling 202.589.1770.



of the Coalition's expenses support its programming.

Statements of Financial Position, December 31, 2014 and 2013

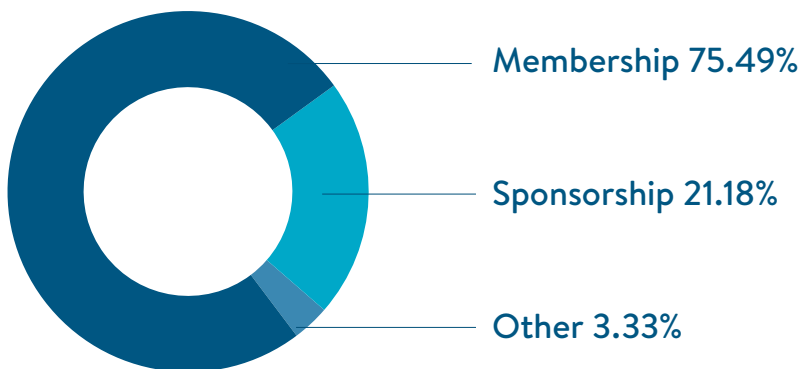
	<u>2014</u>	<u>2013</u>
Assets		
Cash and cash equivalents	\$ 488,097	\$ 528,710
Investments	970,536	505,148
Certificates of deposit	-	431,401
Accounts receivable	72,377	55,721
Prepaid expenses and other assets	5,330	10,878
Property and equipment, net	44,107	50,156
Deposits	8,252	8,252
Total assets	\$1,598,699	\$1,590,266
Liabilities and Net Assets		
Liabilities		
Accounts payable	\$ 68,046	\$ 43,285
Accrued expenses	36,475	3,703
Deferred membership dues	232,975	266,050
Deferred rent payable	25,145	26,127
Deferred sponsorship	5,000	-
Total liabilities	367,641	339,165
Net Assets		
Unrestricted	1,231,058	1,251,101
Total net assets	1,231,058	1,251,101
Total liabilities and net assets	\$1,598,699	\$1,590,266

Statement of Activities For the Year Ended December 31, 2014

	<u>Unrestricted</u>	<u>Temporarily Restricted</u>	<u>Total</u>
Operating Revenue and Support			
Membership dues	\$1,500,050	\$ -	\$1,500,050
Sponsorship	421,000	-	421,000
Support for PMC Policy	-	57,166	57,166
Admission fees—non-members	8,994	-	8,994
Released from restrictions	57,166	(57,166)	-
Total operating revenue and support	1,987,210	-	1,987,210
Expenses			
Program services:			
Education:			
State of Personalized Medicine Luncheon	19,119	-	19,119
Membership events	59,193	-	59,193
PMC/BIO Solutions Summit	4,216	-	4,216
Oncology conference	10,000	-	10,000
Business development:			
Membership development	64,216	-	64,216
Sponsorship/membership	21,800	-	21,800
Stationery and printing	27,964	-	27,964
Total program services	206,508	-	206,508
Supporting services:			
General and administrative	1,292,946	-	1,292,946
Professional fees:			
Accounting	67,567	-	67,567
Communications	186,435	-	186,435
Consulting fees	204,195	-	204,195
IT support	49,582	-	49,582
Legal	-	-	-
Total supporting services	1,800,725	-	1,800,725
Total expenses	2,007,233	-	2,007,233

	<u>Unrestricted</u>	<u>Temporarily Restricted</u>	<u>Total</u>
Change in Net Assets from Operations	\$ (20,023)	\$ -	\$ (20,023)
Non-Operating Activities			
Interest and dividends	13,715	-	13,715
Unrealized and realized loss on investments	(5,612)	-	(5,612)
Miscellaneous income	4,955	-	4,955
Depreciation	(13,078)	-	(13,078)
Total non-operating activities	(20)	-	(20)
Change in Net Assets	(20,043)	-	(20,043)
Net Assets, beginning of year	1,251,101	-	1,251,101
Net Assets, end of year	\$1,231,058	-	\$1,231,058

2014 Revenues



“Personalized medicine is our chance to revolutionize health care, but it will require a team effort by innovators, entrepreneurs, regulators, payers and policymakers.”

– Brook Byers, Partner, Kleiner Perkins Caufield & Byers

MISSION STATEMENT

The Personalized Medicine Coalition, 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.



**PERSONALIZED
MEDICINE COALITION**

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