Latest News & Updates from the Personalized Medicine Coalition

Letter from Washington

Launched in 2004 as an educational and advocacy organization to create a friendlier landscape for investment in and adoption of personalized medicine, and now comprising more than 200 institutions from across the healthcare spectrum and across the globe, the Personalized Medicine Coalition (PMC) is well positioned to advance its mission and realize its important goals in 2012.

As we wrote in our strategic plan published in March last year, “Personalized medicine [must overcome] numerous hurdles,” in particular in the areas of regulation, reimbursement and education to advance its mission of providing better healthcare for patients, and to improve the healthcare system. “Decades-long patterns of intertwined and/or misaligned regulations, guidelines, investment, incentives and perceptions must be changed.”

The PMC Board established three priorities to guide the Coalition’s actions:

- Advocate for public policies that will support personalized medicine’s development through scientific, legislative, regulatory and reimbursement-related activities.
- Help educate and build a personalized medicine informed ecosystem.
- Form consensus among personalized medicine stakeholders to promote common goals, notably regarding regulation, reimbursement and education.

To realize this agenda, in addition to its ongoing educational activities in which we explain what personalized medicine is and why all stakeholders should increase their investments in it, the PMC will continue to propose regulatory reforms that accelerate the development of personalized medicine products; outline reasonable and acceptable evidentiary pathways that can underpin supportive reimbursement policies; and create incentives for innovation and adoption of personalized medicine products and services.

The PMC’s public policy agenda is designed to help overcome the obstacles to personalized medicine by better aligning regulatory, reimbursement and educational systems. Building on previous work, notably on comparative effectiveness research and the regulation of codeveloped diagnostic/therapeutic products, this year the PMC will educate policy-makers and develop champions for personalized medicine in Washington, DC, USA and where possible, globally.

The following legislative and regulatory activities are planned:

- US Senate briefing to discuss personalized medicine when Congress considers reauthorizing legislation to fund drug regulation.
- Carefully considered PMC responses to forthcoming US FDA draft guidance documents on codevelopment, tools and clinical trials population enrichment.
- Advocacy on behalf of the PMC’s legislative specifications to incentivize personalized medicine, including a federal public–private personalized medicine advisory committee, a clear path for codeveloped products at the FDA, rapid coverage for those products at Centers for Medicare and Medicaid Services, and tax credits for companies that invest in their development.
- Based on our previous work on Comparative Effectiveness Research in Congress and with the Patient Centered Outcomes Research Institute (PCORI) in the USA, continued advocacy for personalized medicine consideration in future PCORI research projects by monitoring their work and responding to their actions.

Edward Abrahams

1225 New York Avenue, NW, Suite 450,
Washington, DC 20005, USA
Tel.: +1 202 589 1770
Fax: +1 202 589 1778
eabrahams@personalizedmedicinecoalition.org

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In the meantime, we are proud of our progress so far, outlined in *The Case for Personalized Medicine* [101], and highlighted in our fact sheet ‘*Personalized Medicine by the Numbers*,’ [102] both published at the end of last year.

**Edward Abrahams, President,
Personalized Medicine Coalition**

Websites

- 101 Personalized Medicine Coalition.
www.personalizedmedicinecoalition.org/sites/default/files/files/Case_for_PM_3rd_edition.pdf
- 102 Personalized medicine by the numbers.
www.personalizedmedicinecoalition.org/sites/default/files/files/PM_by_the_Numbers.pdf