

**President's Council of Advisors on Science
and Technology
Personalized Medicine Subcommittee**

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- Trade Association for the U.S. Venture Capital Industry
- Mission: Foster greater understanding of the importance of venture capital to the U.S. economy; support entrepreneurial activity and innovation
- Offers a unique perspective on health care policies for emerging medical therapies and technologies given the close relationship with small start up companies – the true drivers of innovation

Venture Capital Role in the Development of Medical Innovation

- Venture capital is the backbone for disruptive medical therapies and technologies
 - is committed to growing the life sciences sector, finding cures to combat major diseases and advancing medical innovation
 - 28% of all venture capital investment =2006 =\$7 billion
- Venture backed life sciences companies produce enormous health gains, promote cost savings and create jobs
- Venture capital drives the next generation of cures – including personalized medicine
 - Small companies need access to capital
 - Focus on novel therapies and technologies

NVCA's Health Policy Position on Personalized Medicine

- Patient access to innovative therapies and technologies is an important element in improving outcomes and quality of our health care system
- Novel therapies and technologies represent the most important clinical breakthroughs that will significantly improve outcomes and quality of life for millions of patients
 - Personalized medicine is on the cusp of dramatically improving medicine and healthcare
- These technologies can ultimately help drive down health care costs
- Future investment in advancing medical innovations depends upon a balanced and predictable regulatory environment

Molecular Diagnostic Technologies are the Future of Medicine

- New molecular diagnostic technologies will:
 - Make personalized medicine a reality
 - Lead to better health outcomes
 - Lower the cost of healthcare
 - Reduce adverse events

Barriers to the Advancement of Personalized Medicine

- Strong intellectual property protection being threatened by current Congressional legislation
 - Threatens small innovative companies ability to get funding
- FDA Regulatory Uncertainty
 - Unpredictable approval process = less VC funding
 - Example: IVDMIA FDA draft guidance
 - Investors need to evaluate the risks & benefits of a potential investment
 - FDA's ability to keep pace with advancing technologies

Barriers to the Advancement of Personalized Medicine continued...

- CMS Reimbursement Challenges
 - Most molecular diagnostic coverage policy is determined by local Medicare contractors. Coverage may vary from region to region
 - Criteria for Medicare coverage are poorly defined
 - No clear methodology for payment of new tests
 - New tests lack CPT codes
 - Billing rules limit ability of molecular diagnostics to bill Medicare directly for tests

Recommendations to Overcome the Obstacles

- Ensure that Congress passes legislation that will ensure strong IP protection for small innovative companies
 - Strong IP protection is critical for investment into new biomedical therapies and technologies
- FDA Regulatory
 - Work with key stakeholders to develop the appropriate regulatory approval pathway
 - Develop consensus-based guidelines for generating and evaluating efficacy evidence
 - Increase FDA's base funding to improve its ability to evaluate the next generation of medicine

Recommendations to Overcome the Obstacles continued ...

- CMS Reimbursement
 - Coordinate evidence requirements at CMS and FDA to reduce demands on companies and streamline reimbursement pathway
 - Update coding process and payment methodologies to account for high-value diagnostics
 - Create more effective payment pathways for new technologies to encourage adoption and evidence development

Thank You

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