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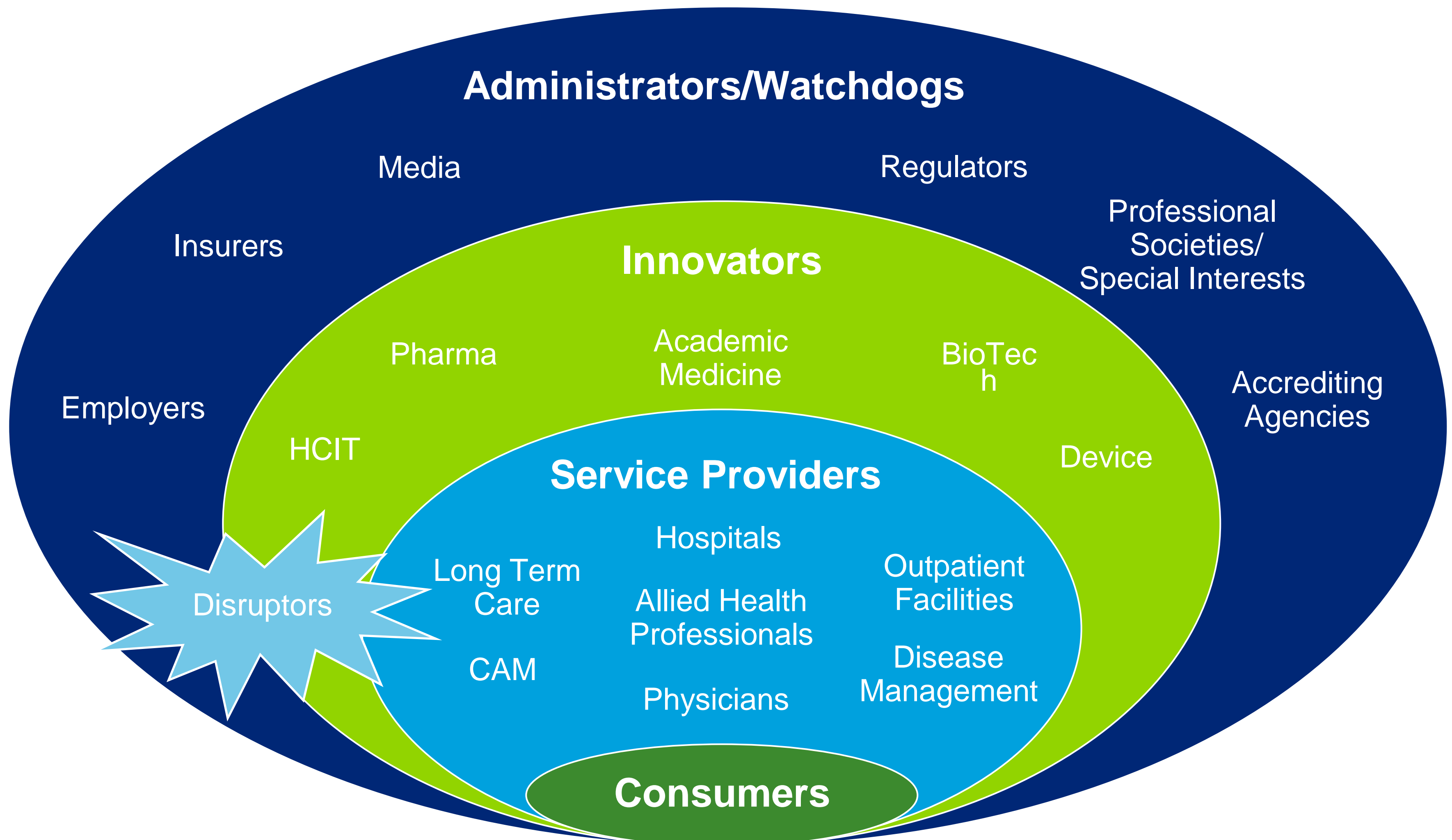
Personalized Health Care: Why Should We Care?

September 19, 2011

Framework: the U.S. health system: fragmented, expensive, complex

Compound growth rate of 7% per year, 17.6% of U.S. GDP



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Complicated regulatory, political framework

The Affordable Care Act's (ACA's) implementation will span 5 election cycles and occur simultaneous with efforts to reduce the federal deficit, restore economic growth, and reduce unemployment

Economic recovery, Clinical Innovation, Demand

2010 - 2013

Rules, Regulations & New Funding

Insurance compliance: MLR, premiums, coverage

Coordination: state-federal governments, agencies

Rules, guidelines, task forces, agencies

Excise taxes—insurance, medical devices, drug companies

2014 - 2016

Mandates, Pilots & Exchanges

Individual mandate

Health exchanges

Employer pay or play

Demonstration/pilot programs:

- *Accountable care organizations*
- *Value-based purchasing*
- *Episode based payments*
- *Medical home*

2017 +

"New Normal"

Physician-hospital alignment

Industry convergence

Convergence: Public health & delivery system

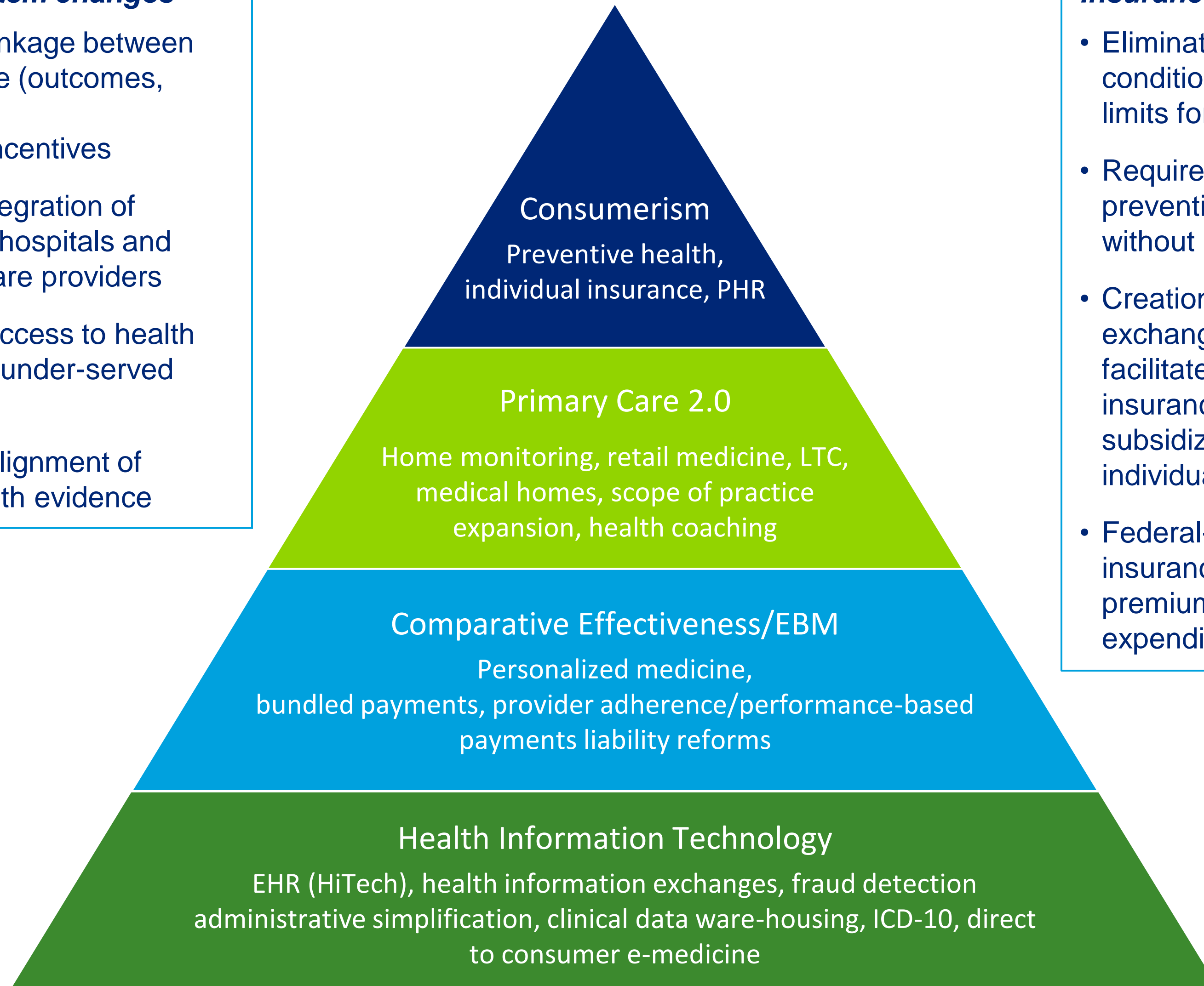
Volume to value

ICD-10, Electronic Medical Record, Comparative Effectiveness implementation

Structure: intended delivery, payment system changes

Delivery system changes

- Increased linkage between performance (outcomes, costs) and payments/incentives
- Increase integration of physicians, hospitals and long term care providers
- Increased access to health services by under-served populations
- Increased alignment of coverage with evidence



Insurance system changes

- Elimination of pre-existing condition, lifetime and annual limits for insurance plans
- Required coverage of preventive health services without co-payments
- Creation of health insurance exchanges in each state to facilitate access to affordable insurance and manage subsidized purchases by individuals and employers
- Federal-state regulation of insurance plan coverage, premiums, and medical expenditures

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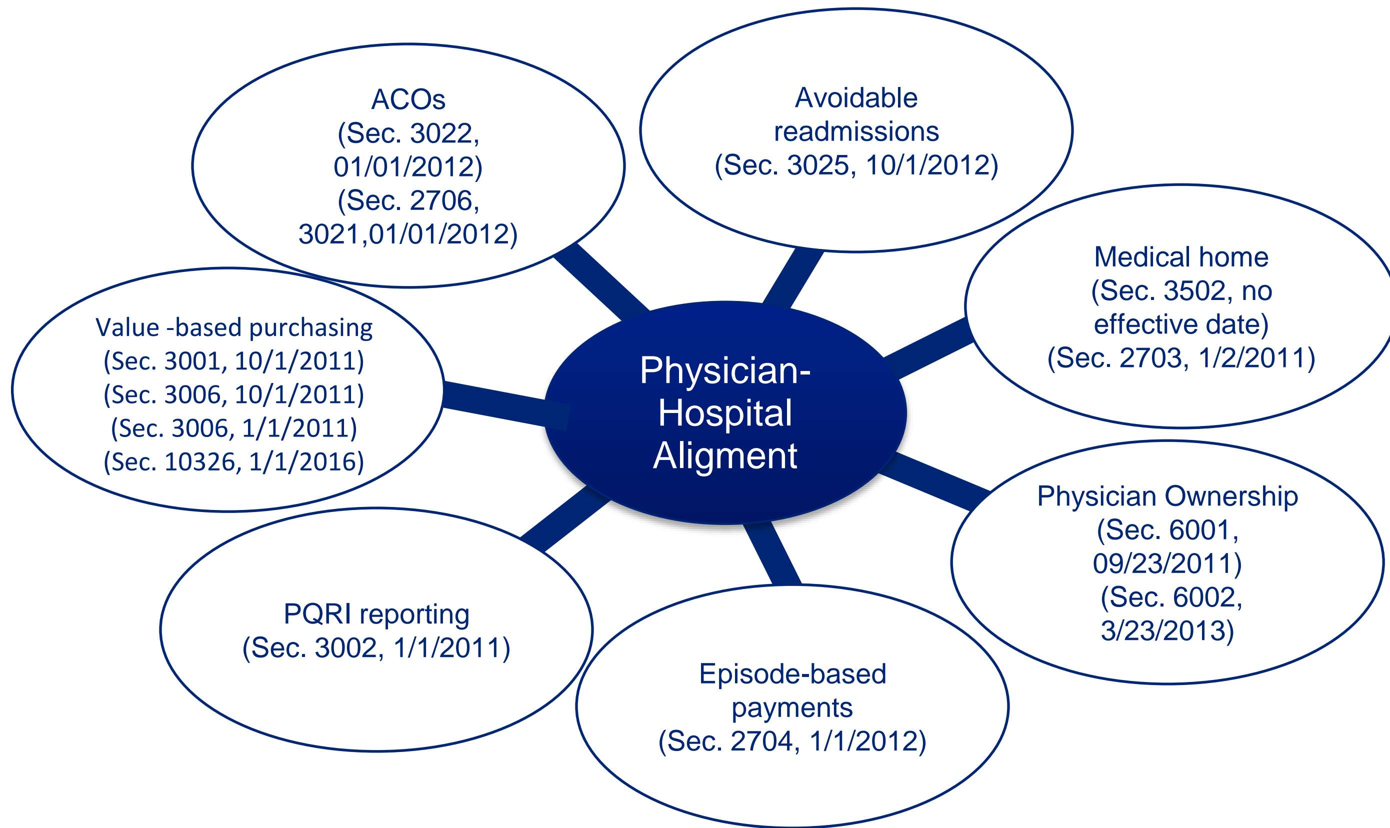
Central feature of reform: integrated health systems paid for value based on quality, cost containment and consumer experience



Clinical Integration Operational Competencies	*Risk-based Contracting Operational Competencies*
• Evidence-based guidelines embedded in clinical IT applications system wide • Quality management and measurement: safety, outcomes, efficacy • Shared governance: physician-hospital alignment • Gain-sharing-based compensation for providers	• Contract negotiation, adjudication and distribution of funds • Medical management: provider credentialing and performance reviews • Provider discipline • Quality, cost reporting • Patient adherence management

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Three new agencies will play key roles in personalized medicine

CMS Center for Medicare and Medicaid Payment Innovation	Independent Payment Advisory Board (IPAB)	Patient-Centered Outcomes Research Institute (PCORI)
• Test innovative payment and service delivery models • Broad authority to determine what models will be tested, in what populations, and for how long, with a preference for models that address deficits in care leading to poor clinical outcomes or potentially avoidable expenditures	• The purpose is to reduce the per capita rate of growth in Medicare spending • Operates independently of MedPAC • Recommendations take effect absent Congressional action • May recommend changes to Part D to generate required savings	• Broad scope of research (drugs, devices, procedures, delivery system) with a focus on clinical effectiveness research • Findings are not coverage/ payment recommendations, but can be used by HHS to inform coverage

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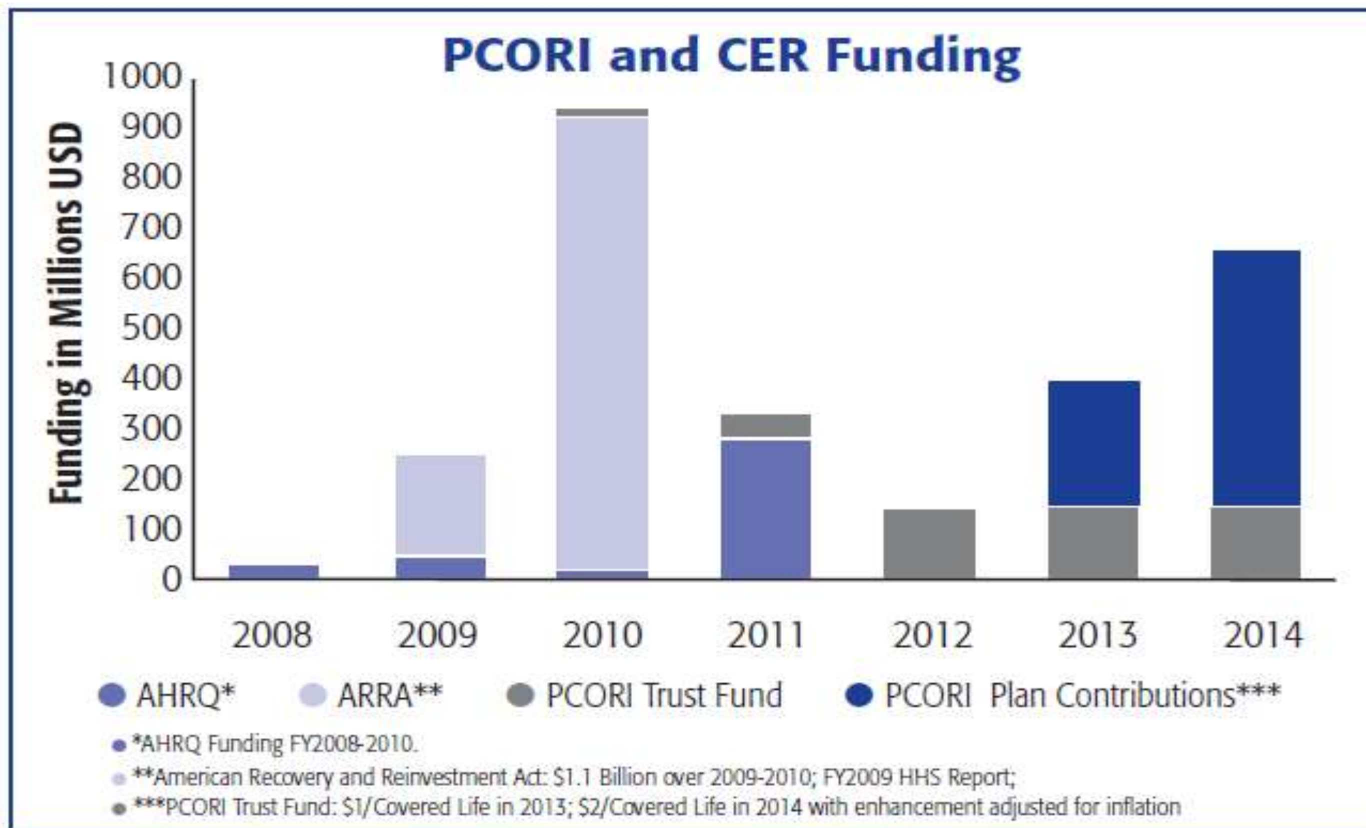
CER mandate in ACA

- **Financed through Patient-Centered Outcomes Research Trust Fund (PCORTF)**
  – PCORTF funded through ACA appropriations through 2012
  – From 2013-2019, PCORTF will receive an annual appropriation of $150 MM, supplemented by fees imposed on Medicare and private payers



National Pharmaceutical Council. The Patient-Centered Outcomes Research Institute Resource Guide. Nov 2010.

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IOM: system wide goals

- **Evidence Based *Personalized Medicine***
- **Patient Centered Approach**
- **System Orientation**

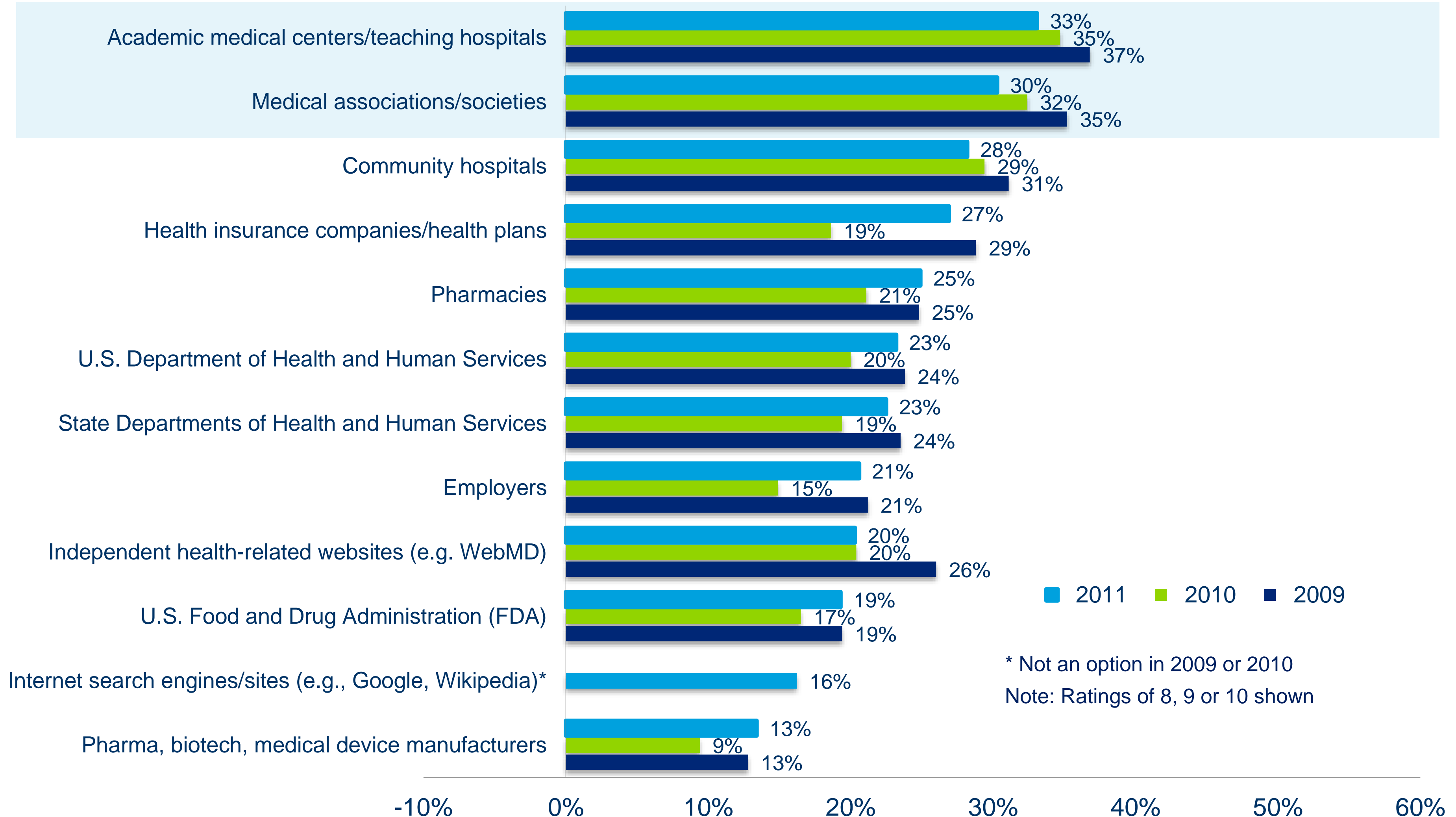
- 20,000 biomedical journals
- 150,000 articles/month
- 300,000 RCTs published

So who cares?

How do key stakeholders view personalized medicine?

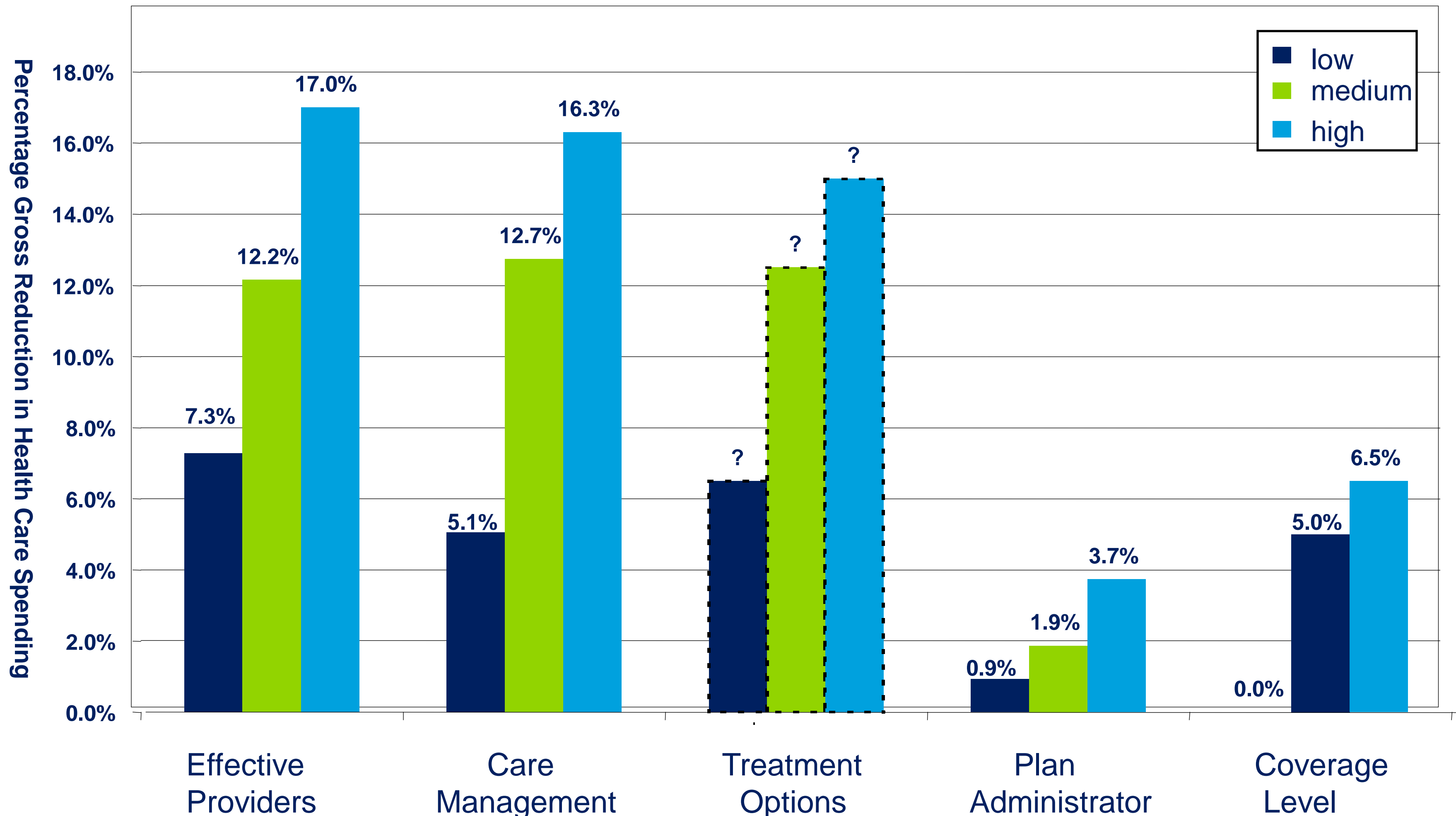
Consumers: most depend on clinicians (few investigate for themselves) and most assume it's all "personalized"

Most trusted sources of information for safety and effectiveness of medical treatments



2011 Global Survey of Health Care Consumers, Deloitte Center for Health Solutions

Plans: Savings potential & clinical differential clear, but when and for whom



Vanderbilt Center for Evidence-based Medicine
www.ebm.vanderbilt.edu

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Biopharma: clear opportunity, but an uncertain business climate for R&D

Translation Research

- Academic medical centers and research institutes have outpaced LS companies in adoption of translation research
- Life sciences R&D has been hampered by lack of access to patient clinical data

" Any clinical trials should start with feasibility modeling using informatics and patient clinical data. Optimizing the inclusion & exclusion criteria can save millions of dollas"

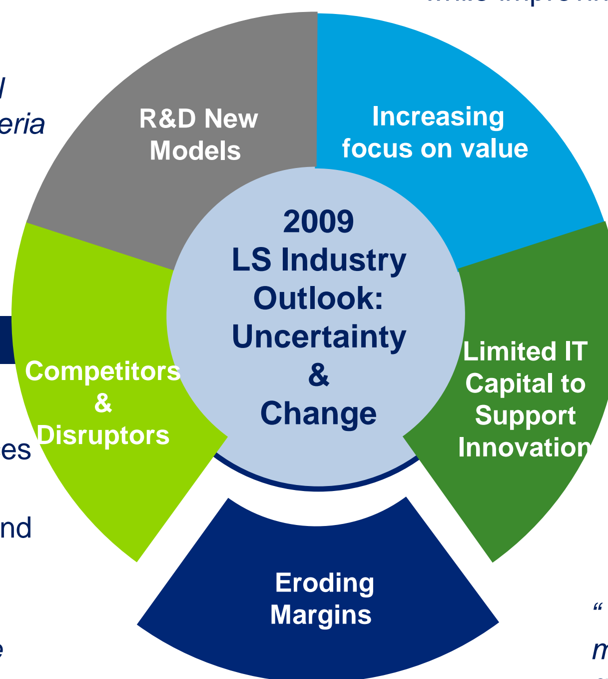
- VP, evidence-based medicine, a major med. device company

Comparative Effectiveness

- The push for comparative effectiveness has gained traction among policy makers
- Provisions on comparative effectiveness are included in the health reform plan of presidential-elect Obama.
- Cost effectiveness will probably as a way of reining in costs while improving quality

" We already have adequate longitudinal EHR data to support clinical and economic studies of drugs. We will conduct comparatives studies, publish the results , and help physicians make a better choice of medicines for patients.

- CIO, a large health system



Vulnerability to Competition

- Branded drugs will be off the patent
- Bio-similarities and Low-end medical devices continue to take more market share
- Basis of competition shifts toward quality and value

" Our market share is decreasing due to the entrance of low-end products. If we can't use patient-level data to generate evidence to demonstrate the better safety of our products, we will lost millions of dollars in revenue"

- Director, marketing, a major med. device company

Information Management

- Declining margins and investment returns greatly restrict access to capital
- Reduced IT budget requires strategic planning and sensible investments to support innovation

" Given the current economic situation, we must make sensible IT investments. We are under great pressure to demonstrate ROI.

- IT Director, a biotech company

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Personalized health care: why should we care?

- Because the public trusts academic medicine to deliver
- Because the industry needs independent confirmation of its science
- Because it’s a global market opportunity
- And it’s the right thing to do!

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