



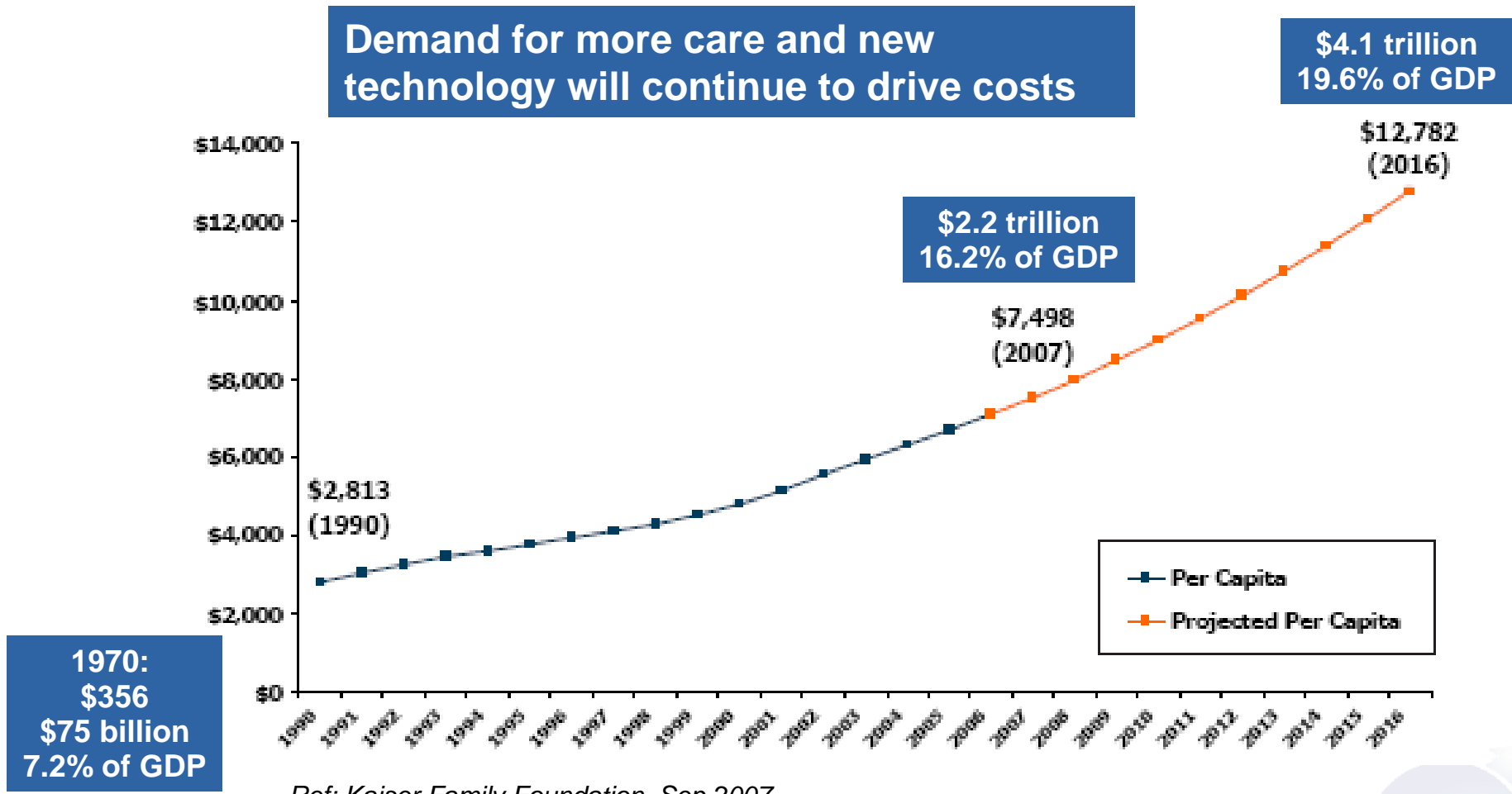
Reimbursement Strategy for Early Stage MedTech Companies – Do It Early

David Barone
Principal

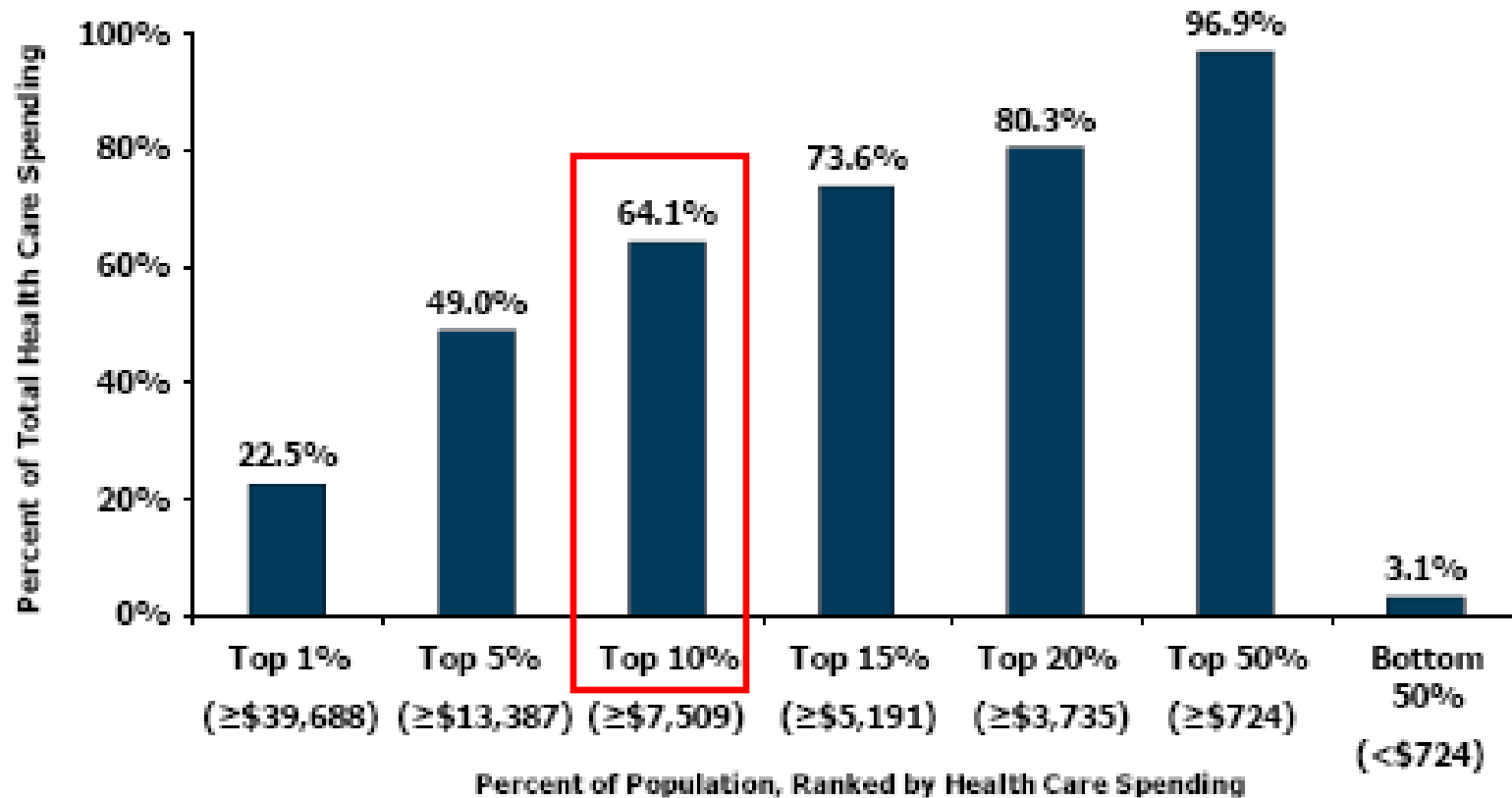
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Healthcare Expenditures / Per Capita



Expenditures are Concentrated



Ref: Kaiser Family Foundation, Sep 2007

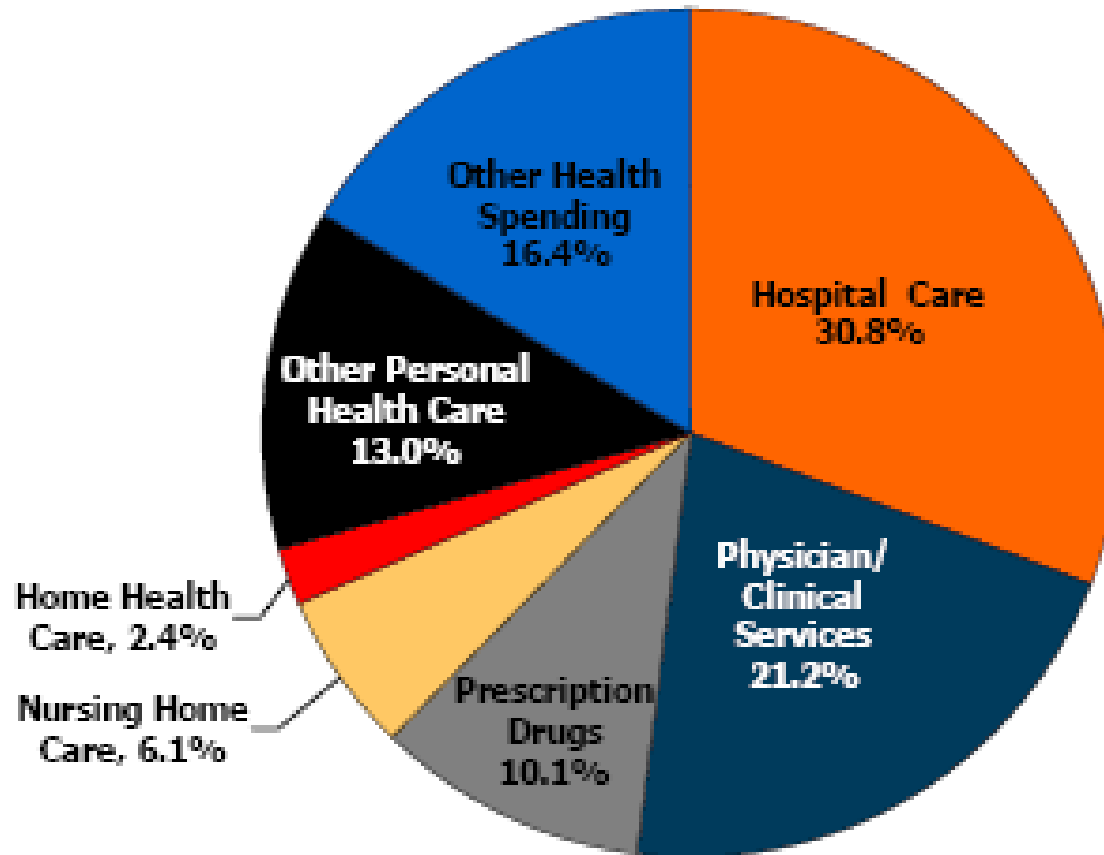


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Distribution of Expenditures (by type of service)



Ref: Kaiser Family Foundation, Sep 2007

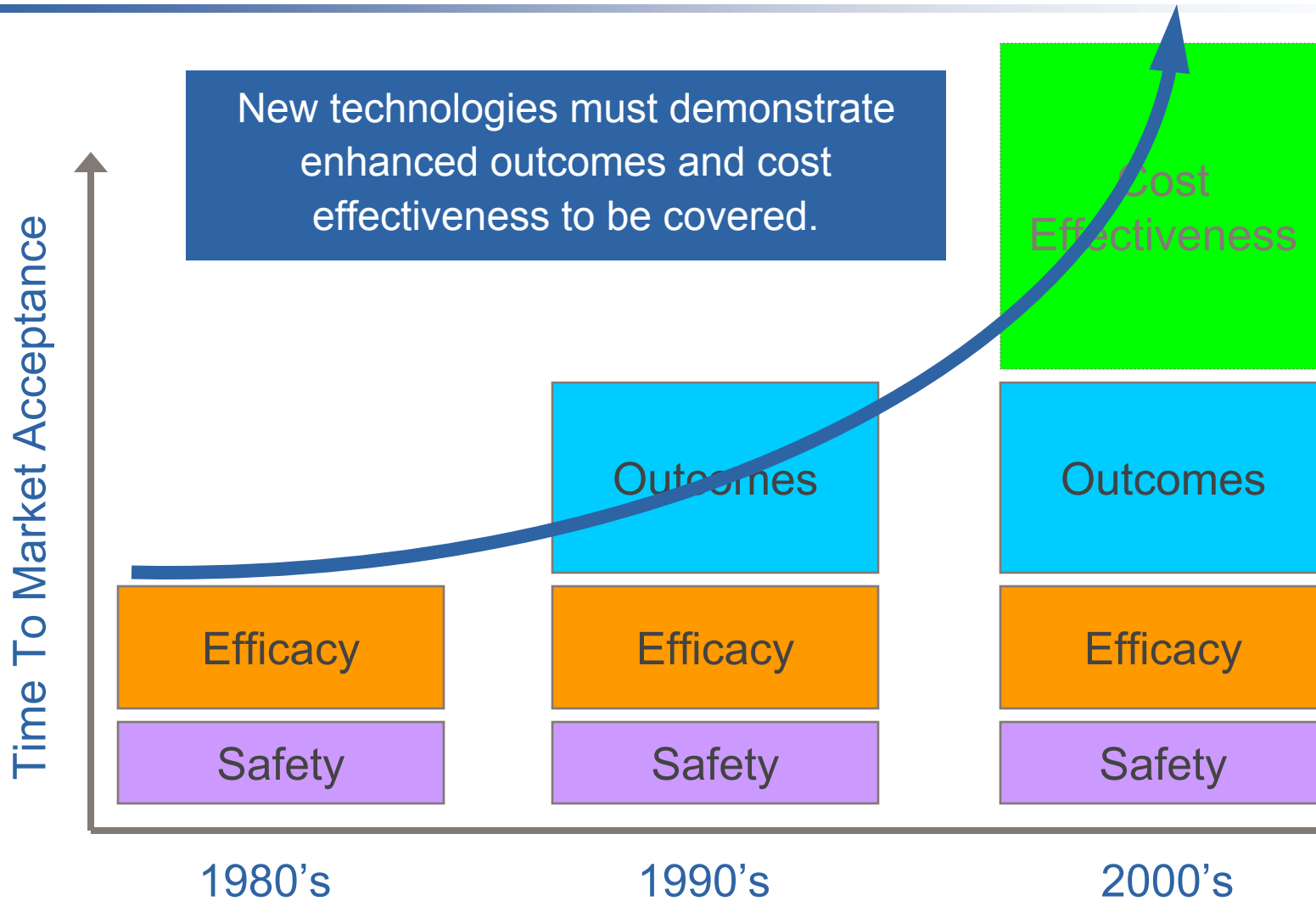


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New Market Barriers



FDA and Payers are Looking for Different Benefits



FDA

Does the product do what it claims?

- Safety and efficacy
- Data generated in controlled setting
- Academic focused review / KOL
- Scientific method
- No cost considerations



Payers



Does the product / procedure improves outcomes?

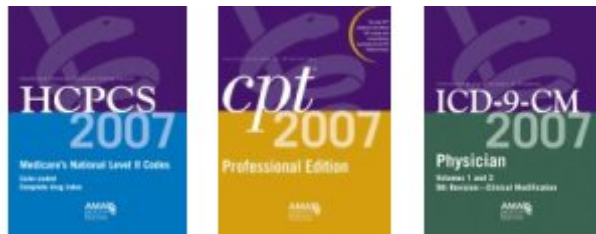
- Reasonable and necessary
- “Real World” / non-academic evidence
- Professional societies input is important
- No standard methodology for determining coverage
- Cost is often key consideration

The Reimbursement Process

I. Coding ➡ II. Coverage ➡ III. Payments

Classifies patient conditions, services and supplies

- DRG (~500)
- HCPCS (~15,000)
- Drugs and Biologics



Defines when products & services are eligible for payment



Determines payment processes and amounts

Medicare Fees:

- Standardized
- Public
- Non-negotiable

Commercial Payers:

- Non-standardized
- Confidential
- Negotiable

Obtaining a New CPT Code

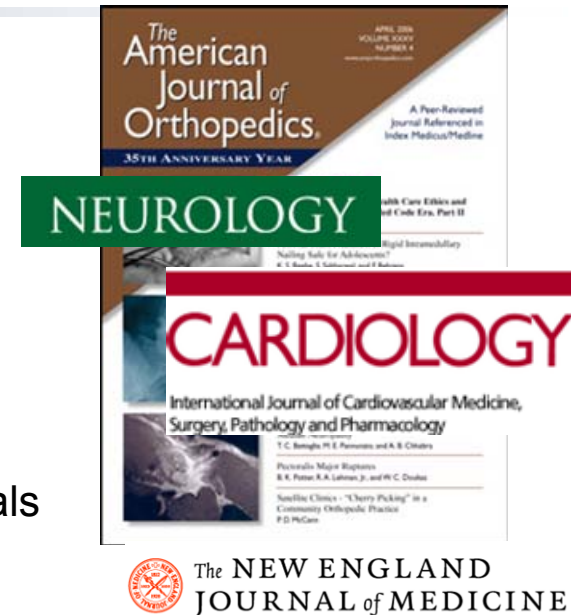
Criteria

1. FDA approval for the specific use of the device / drug
2. Truly new service / procedure
3. The clinical efficacy has been well-established
4. The service is widely performed across the country
5. Used by many physicians or other healthcare professionals

Requirements

- ✓ Peer-reviewed literature (US publications only!)
- ✓ Specialty societies support
- ✓ Understanding the political landscape

Need a New Code?...It can take 3-5 years



Coverage Criteria *



1. Final regulatory approval
2. Scientific evidence – effect of the technology on health outcomes
3. Must improve the net health outcome
4. Must be as beneficial as any established alternatives
5. The improvement must be attainable outside the investigational settings

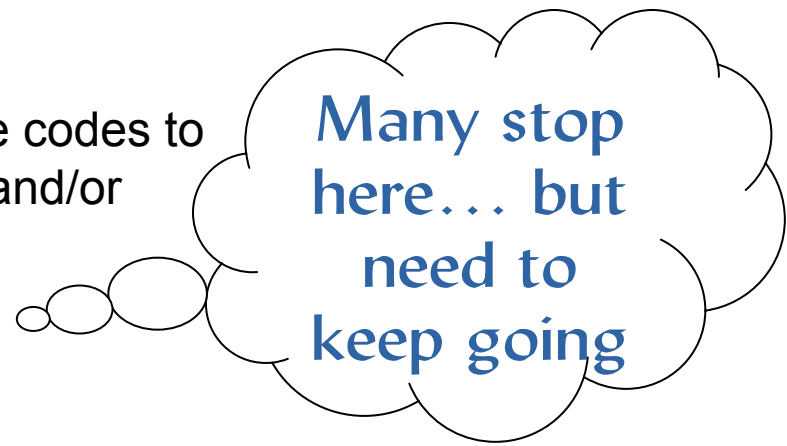
Health Outcomes

- Increase lifespan
- Reduce care of chronic disease
- Enhance quality of life
- Improve functional ability

* Technology Evaluation Center (TEC), used by Blue Cross and Blue Shield Association

Reimbursement Review: The Early Homework

- Presence or absence of appropriate codes to identify and reimburse the product and/or corresponding procedures
- Coverage guidelines by CMS and commercial payers
- Codes and coverage guidelines for competitive procedures / products
- Potential impact of regulatory or legislative initiatives potentially affecting reimbursement for the new technology



Goals of Reimbursement Strategy

- Improving product development, regulatory and clinical studies/ plans
- Identifying proactive steps to remove or mitigate the effect of payment barriers
- Ensuring that customers of the product can obtain maximum reimbursement for the corresponding service
- Explore revenue generation options until full reimbursement is available (can take a few years)



Define Your Tactics

- Clinical studies and development of evidence
- Key opinion leaders to interact with insurers and coding bodies
- Relationships with appropriate specialty medical societies
- Economic models to prove cost effectiveness to insurers

Continuing Efforts

- Improve the quality of evidence
 - Leading peer-reviewed journals
 - Well-designed studies
 - Multiple patient demographics
 - Cost impact
- Continue payers' education
 - Information packages describing specific diseases and patient populations treated
- Work with professional societies, especially when technology crosses many specialties



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