Time-to-Adoption

Reimbursement as a Marketing Strategy Paradigm

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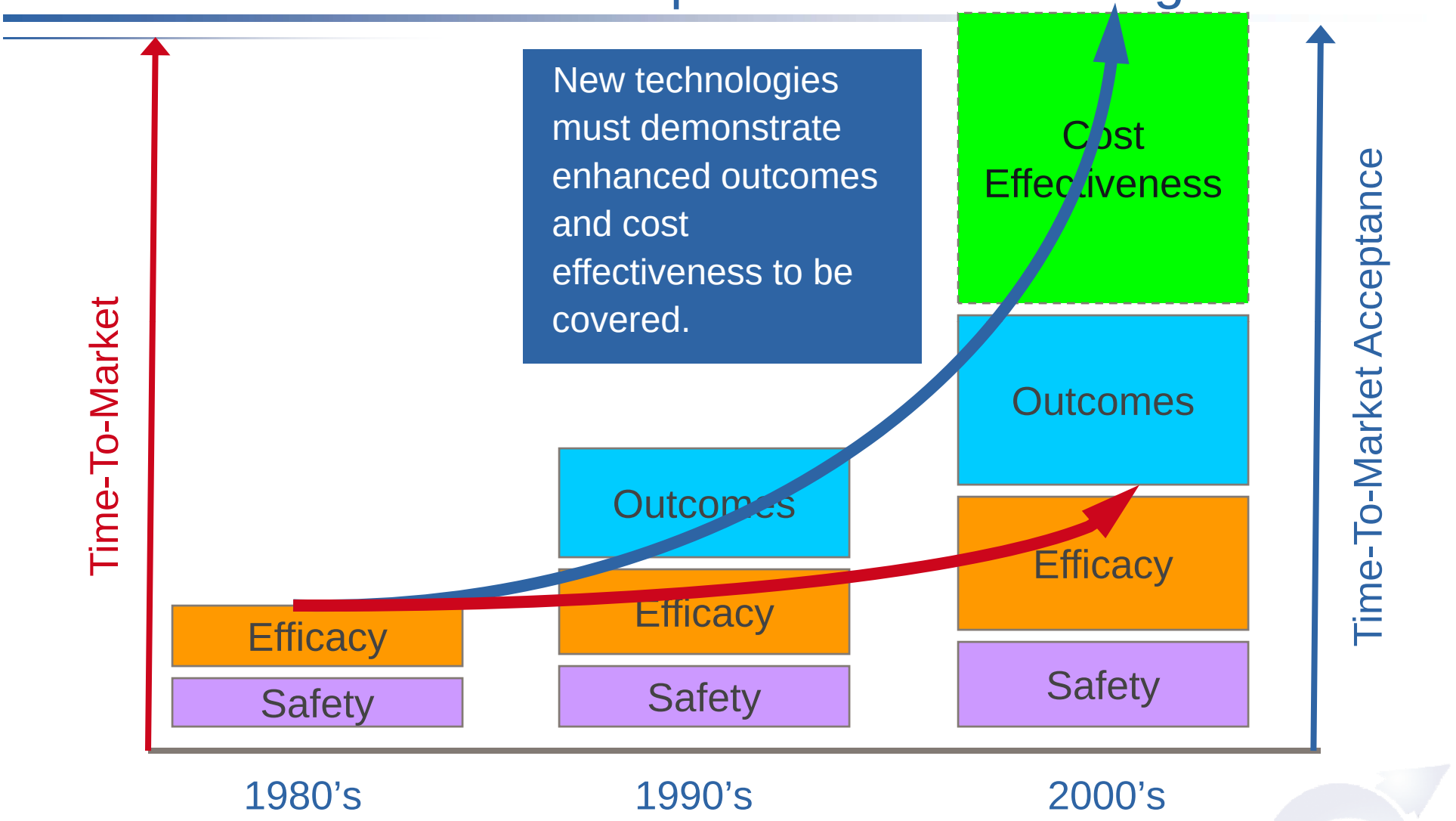
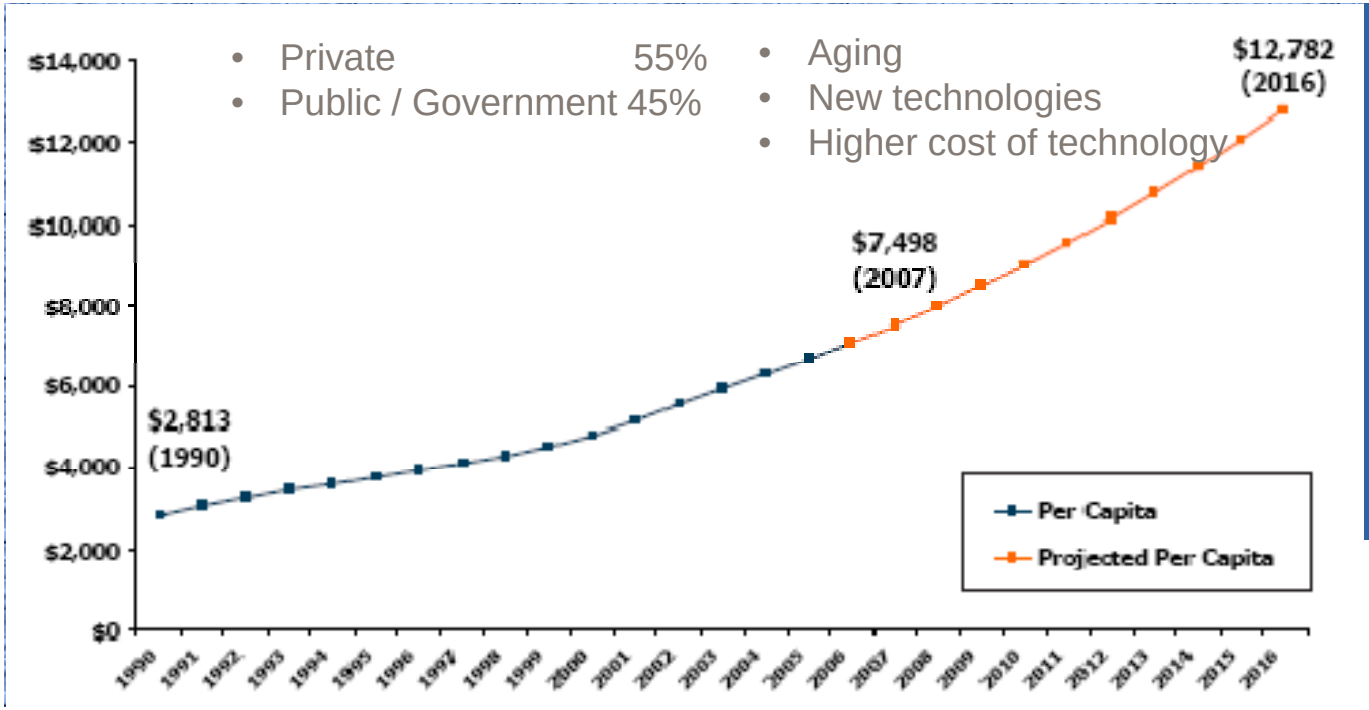
Time-To-'Market Acceptance' is Increasing



Considerable Implications

- Need additional funds and financing rounds
- Valuations are impacted
- Slowing business development initiatives
- Prospective distributors sit on the sideline
- Increased risk of new competitors

Healthcare Expenditures Are Mounting

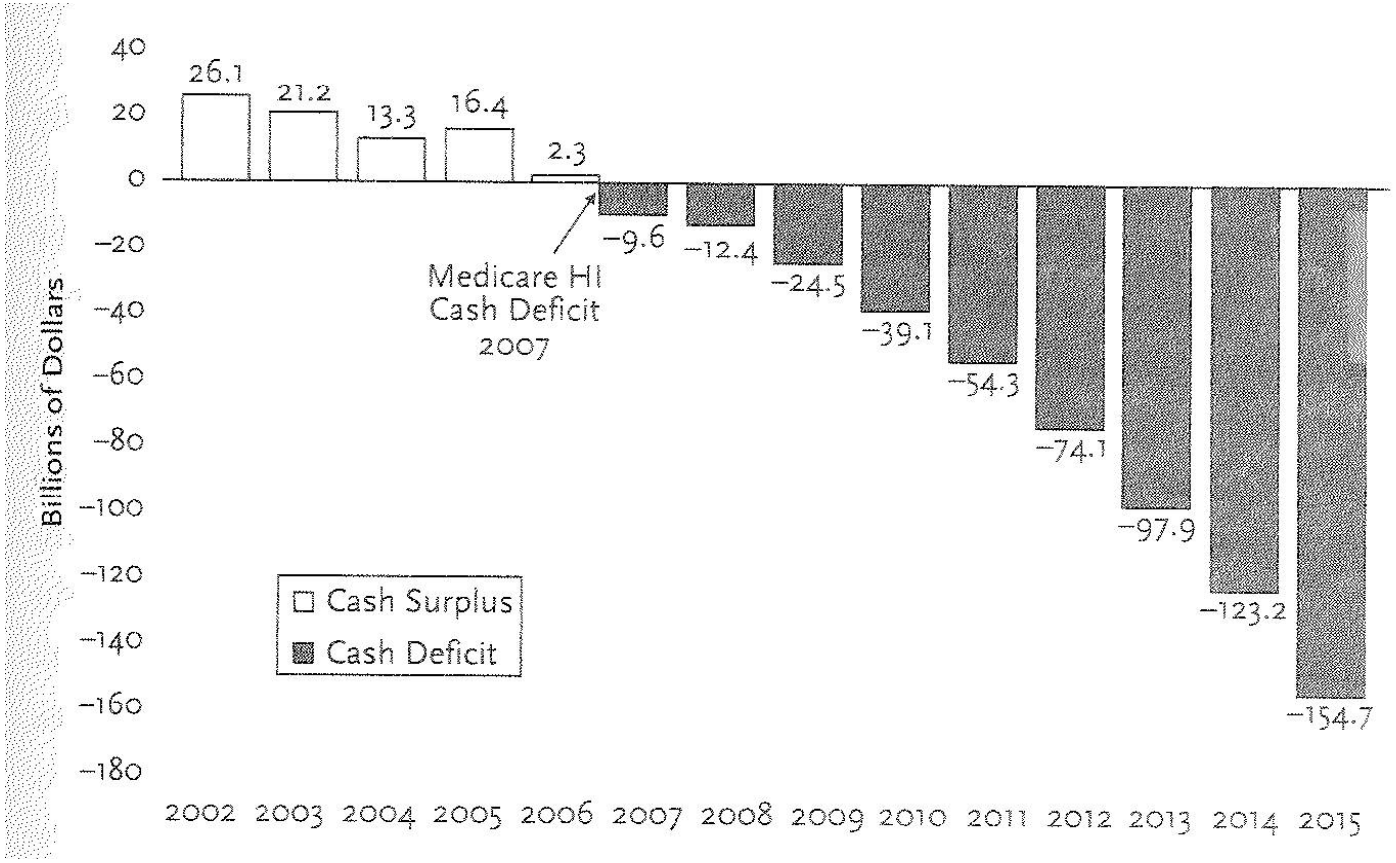


Demand for more care and new technology will continue to drive costs

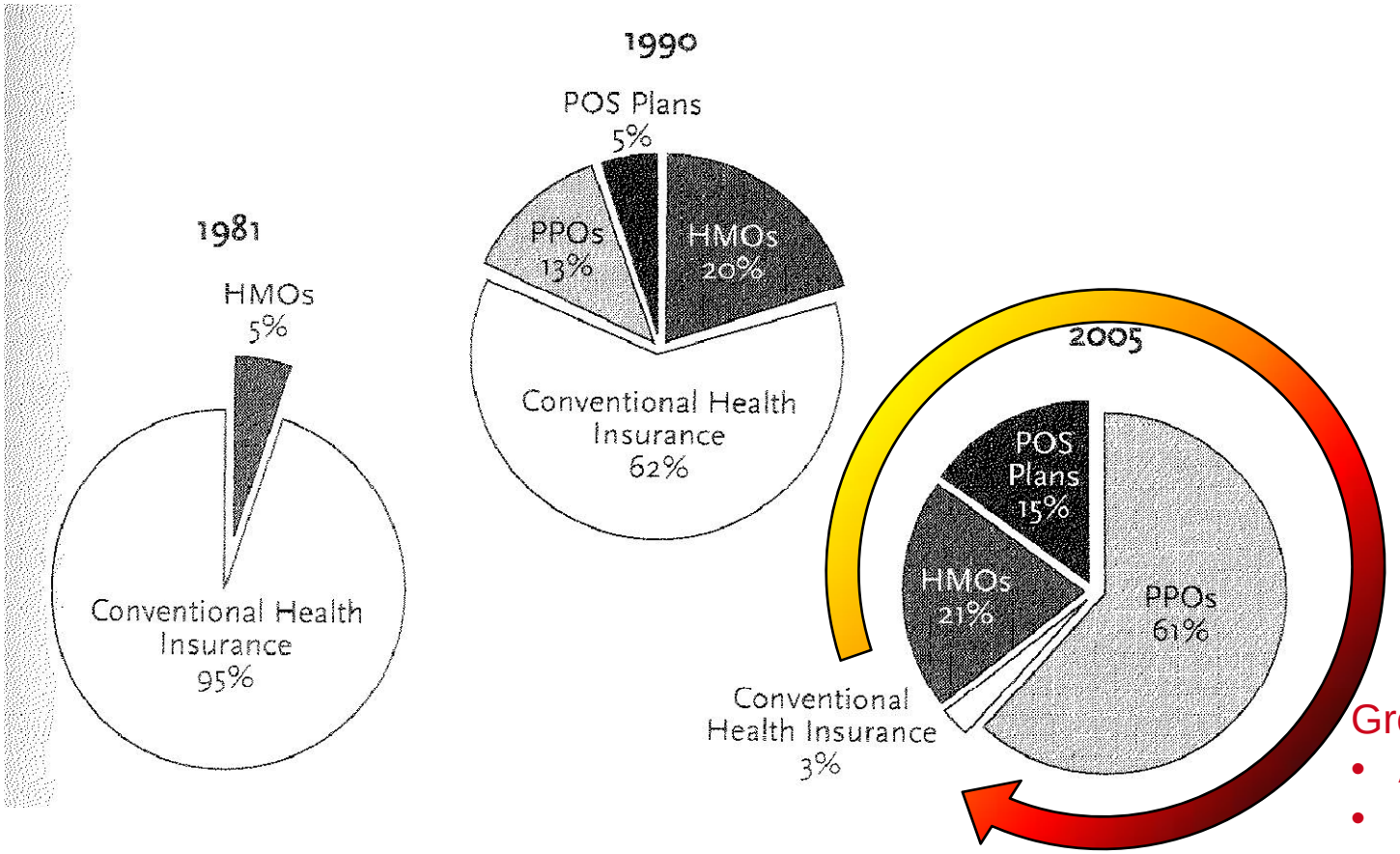
	1970	2007	2016 (p)
Annual cost per capita	$356	$7,498	$12,782
Total Expenditures	75 billion	2.2 trillion	4.1 trillion
% of GDP	7.2%	16.2%	19.6%

Ref: Kaiser Family Foundation, Sep 2007

Net Cash Flow (Medicare) → Political Pressures



Market Response: Managed Care



Greater control of

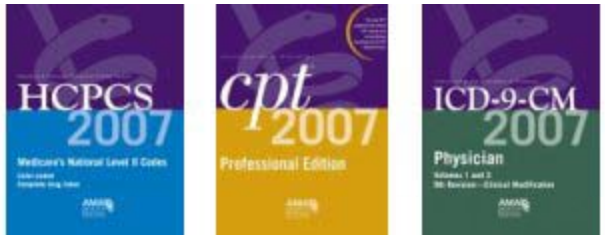
- Access
- Coverage
- Payment

The Reimbursement Process

I. Coding ➡ II. Coverage ➡ III. Payments

Classifies patient conditions, services and supplies

- ICD-9 (~500)
- CPT (~8,000)
- HCPCS (~15,000)
- Drugs and Biologics



Defines when products & services are eligible for payment

Determines payment processes and amounts

<u>Medicare Fees:</u>

- Standardized
- Public
- Non-negotiable

<u>Commercial Payers:</u>

- Non-standardized
- Confidential
- Negotiable

Code ≠ Coverage

Coverage ≠ Payments

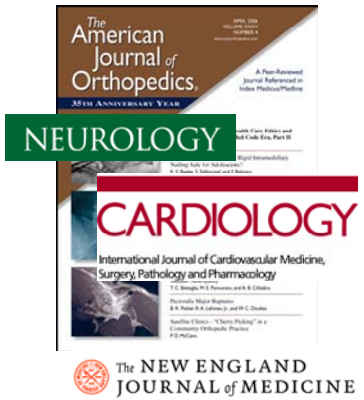
Obtaining a New CPT Code

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
  - Published articles
  - Documenting improved health outcomes
- ✓ Specialty societies support



FDA and Payers are Looking for Different Benefits

FDA

Does the product do what it claims?

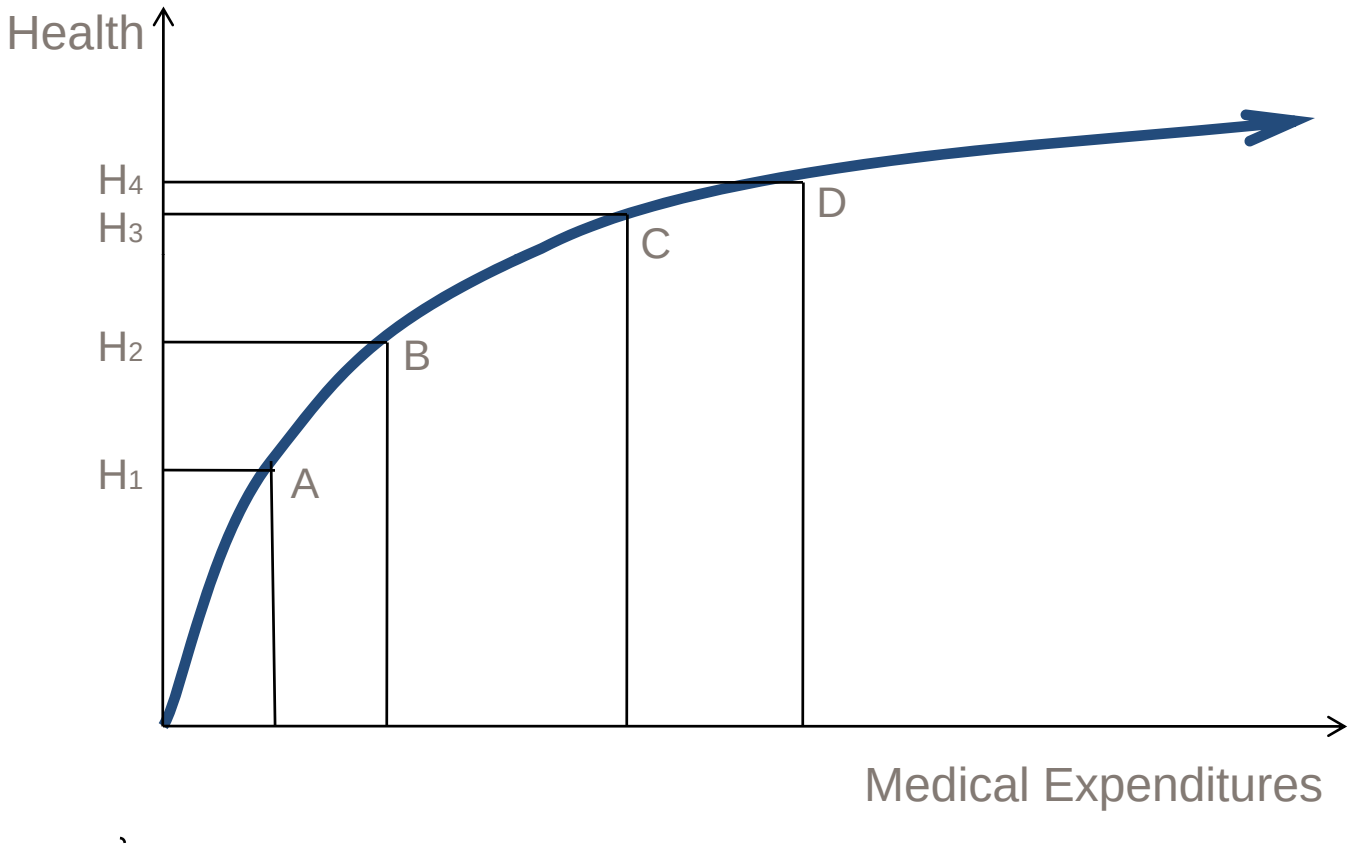
- Safety and efficacy
- Data generated in controlled setting
- Academic focused review / KOL
- Scientific method
- Substantial equivalence or comparison to placebo
- Intermediate or short-term outcome
- No cost considerations

Payers

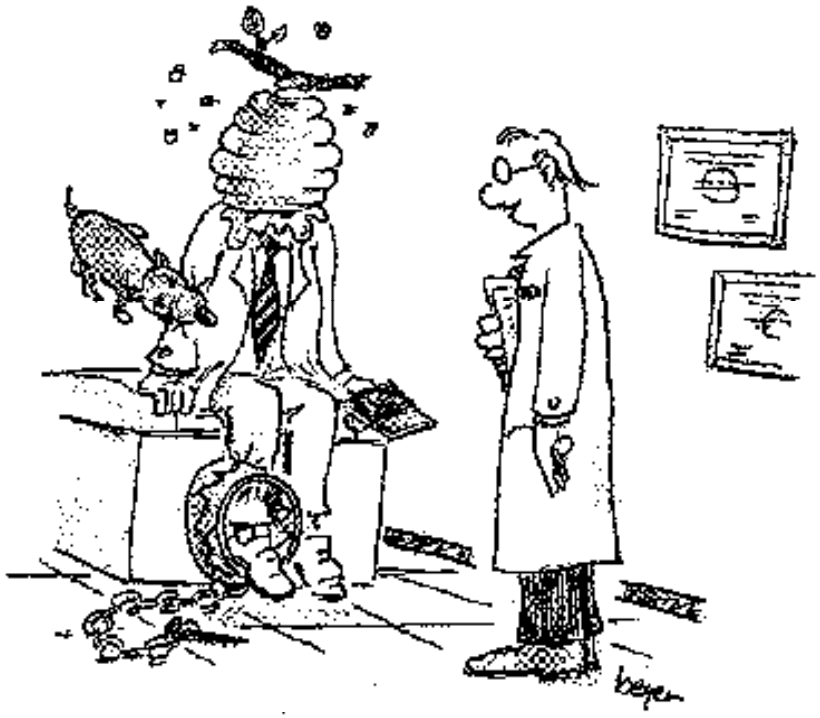
Does the product / procedure improves outcomes?

- …Everything listed on the left, plus
- Reasonable and necessary
- Use in “real world” / general, non-academic and routine conditions
- Professional societies input is important
- No standard methodology for determining coverage
- Long term health outcomes
- Cost is often key consideration

Effect of Increased Medical Expenditures on Health



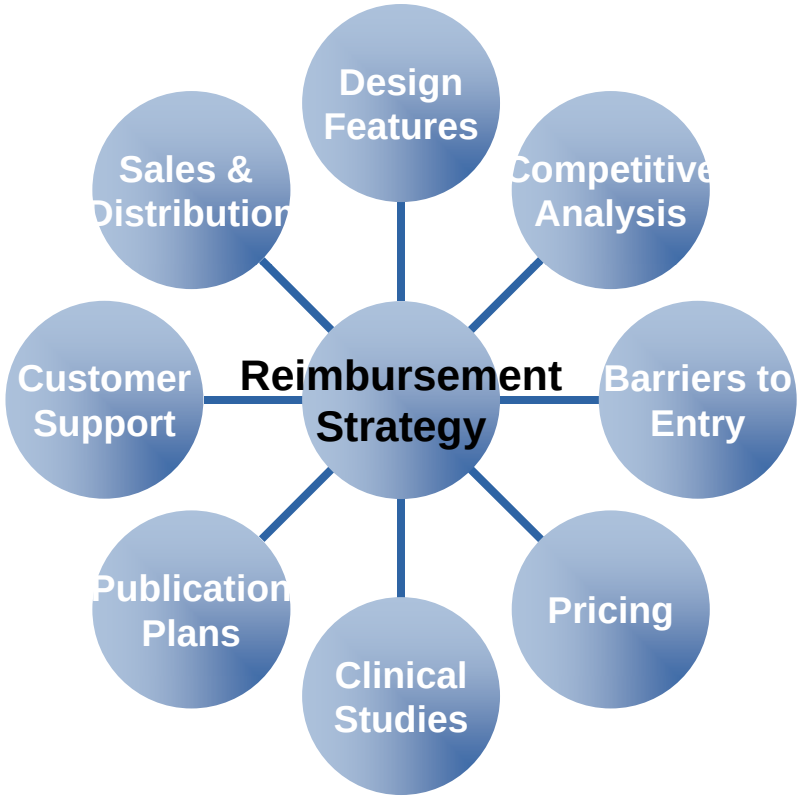
Ref.: Health Policy Issues, PJ Feldstein, 2007



“Your insurance just called. They don’t cover ‘having a bad day’…”

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)



Pre-Product Development Questions

Timing - during product development, and in conjunction with clinical, regulatory and sales and marketing planning

- Product / clinical positioning
  - Who will receive the product and who will be paying for it
  - Who will actually do the procedure and in what settings
  - What indications are most appropriate
  - Target population
  - Anticipated quality and/or efficiency benefits
- How will the product meet FDA “safe and effective” and payers’ “reasonable and necessary” requirements?
- If reimbursement exists, will it cover providers’ expense
- Reimbursement strategy
  - Available codes and coverage guidelines
  - Need to modify existing codes or establish new codes
  - Modifications to coverage guidelines
  - Justifications to payment increase
- Address payers needs when planning studies
  - What data represents evidence-based?
  - What will determine the amount they pay?

Reimbursement Planning

	Similar to Another Product	Expansion of Existing Technology	New / Innovative Technology
Development	Confirm existing codes and coverage	Modify coverage, coding and payments to include the new product	Create new coverage, coding and payment structure for the product
Evidence	FDA approval with same indications suffice for inclusions in existing coverage	1-2 studies	Randomized controlled study (2-4); cost effectiveness data; Registry data
Timelines (post FDA approval)	6 – 12 months	1 – 2 years	2 – 5 years

National or Local Coverage Decisions

NCD

- Risk assessment: “all or nothing” decision
- Positive decision leads to consistent coverage nationwide
- Risk of non-coverage decision or restricted access to treatment
- Private payers often follow national decisions

LCD

- No risk of “all or nothing” decision
- More flexibility in the process
- Standards of coverage vary
- Inconsistent LCD can lead to initiation of NCD

Validate your Reimbursement Early

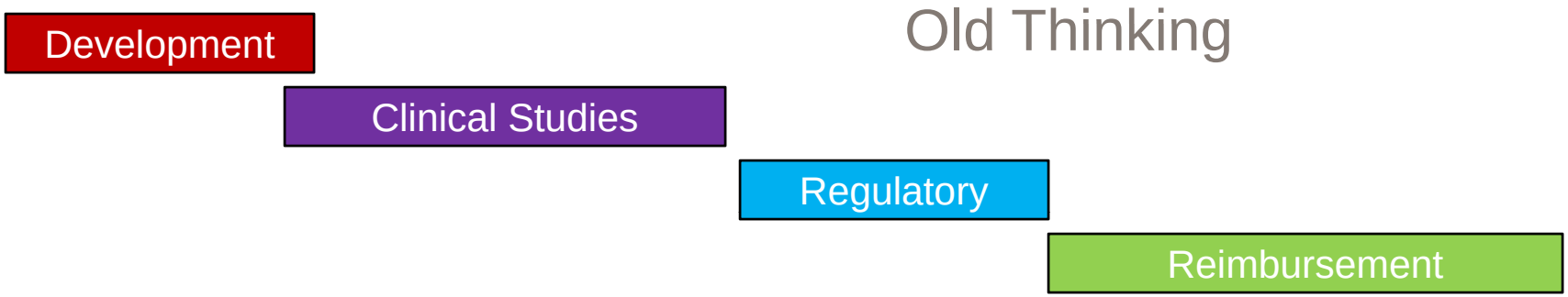
Manufacturers may erroneously conclude that initial coverage suggests their device has been “approved” by a payer, when in fact, the payer may initially reimburse because it didn’t identify the product as new or with expanded indications. The product simply falls below the “reimbursement radar”.

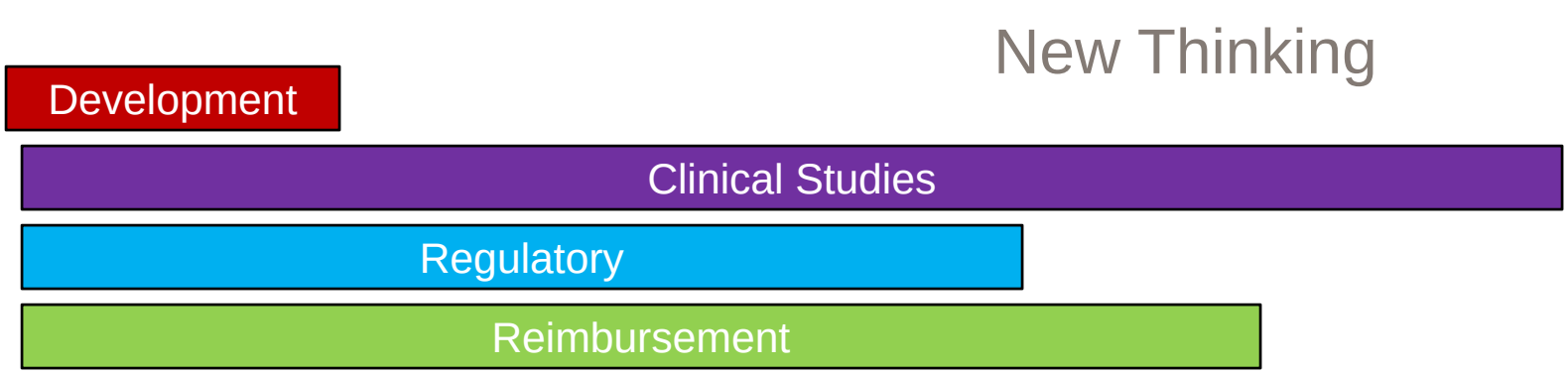
Post Marketing Activities

- Cultivate support from KOL
- Seek position statements from specialty societies
- Educate employers and beneficiaries
- Improve the quality of evidence through additional studies (teaching and community settings)
- Document economic costs
  - Family, employer
  - Complications
  - Models estimating impact on societal healthcare costs
- Develop payers education packets specific to disease and patient population treated
- Follow legislative initiatives

Pre-Reimbursement Marketing

- Continue to develop supportive evidence
- Develop installed base in segments not/less sensitive to third-party payers
  - Early adaptors
  - Provider networks not affected by third party payers (e.g. VA, Kaiser)
  - Inpatients
  - Workers compensation
  - Self pay
  - Participation in covered clinical research (Coverage with Evidence Development)
- Local payers
  - Local opinion leaders
  - Significant providers
  - Use ‘miscellaneous’ codes or ‘modifiers’
- Do not Induce utilization


Old Thinking
Development
Clinical Studies
Regulatory
Reimbursement


New Thinking
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Decision to purchase and decision to use are not the same

Thank You

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