National Policy Challenges for the Device Sector

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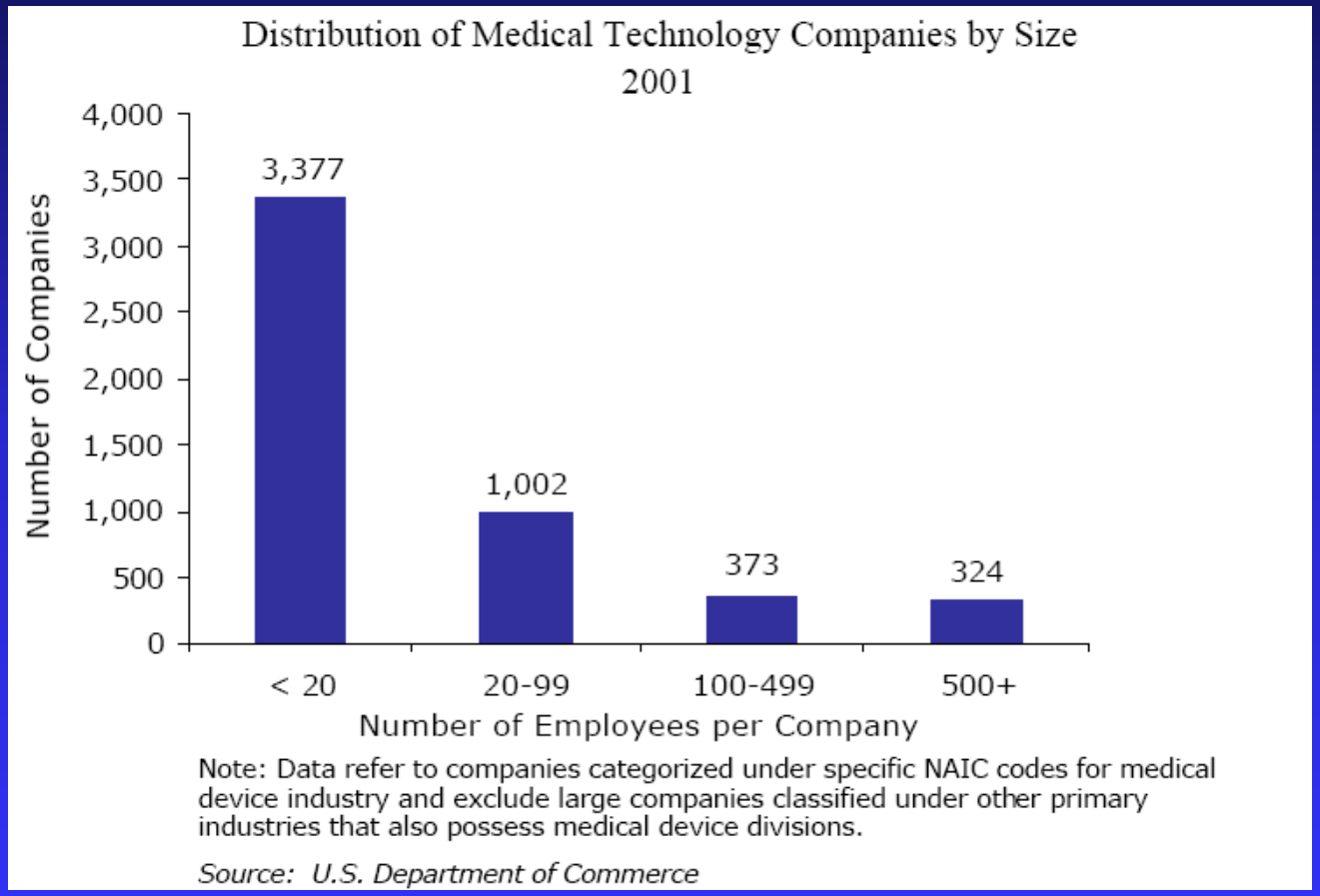
Device Industry

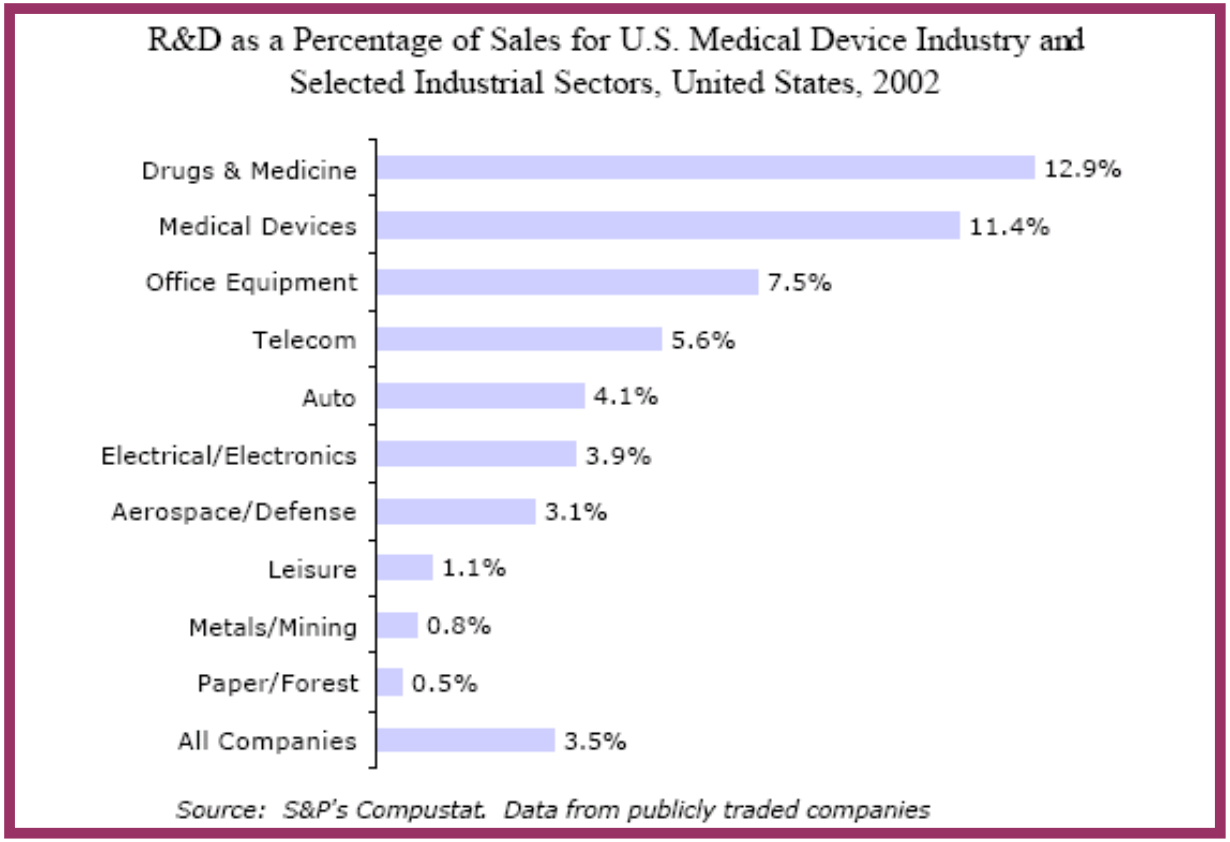
- A Small Company Industry
- A Research Intensive Industry
- An Industry that depends on Innovation
- A Price Competitive Industry

Device Innovation:
A small company industry



Source: Lewin Group, Dept of Commerce, 2004

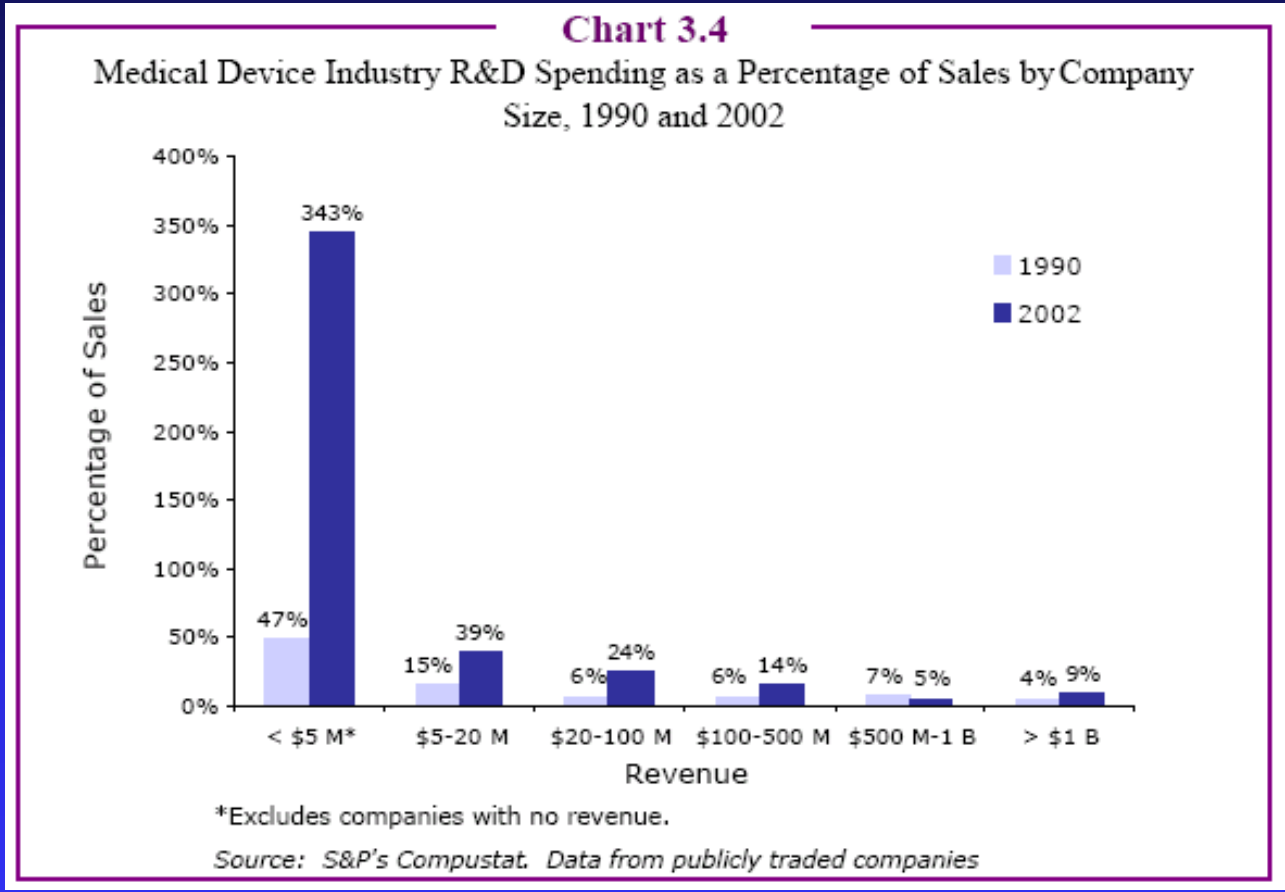
Device R&D



Source: Lewin Group 2004

Small Firms, Big R&D

Small companies invest heavily



Source: Lewin Group 2004

Small Firms, Big Breakthroughs

Big advances often from small firms

- Artificial hips, knees
- Bypass machines
- Glucose monitors
- Ultrasound tests
- Automated blood analyzers
- Mechanical heart valves
- Flexible endoscopes
- Kidney dialyzers

Source: The Wilkerson Group

Device Innovation
Short life cycles

Device Life Cycle = 6 - 24 months

Pharma Life Cycle = 7 -10 years

Source: Lewin Group, 2000, 2004; Gelijns, IOM, 1990; Kahn, IOM, 1991; Glover, 2002

Device Innovation

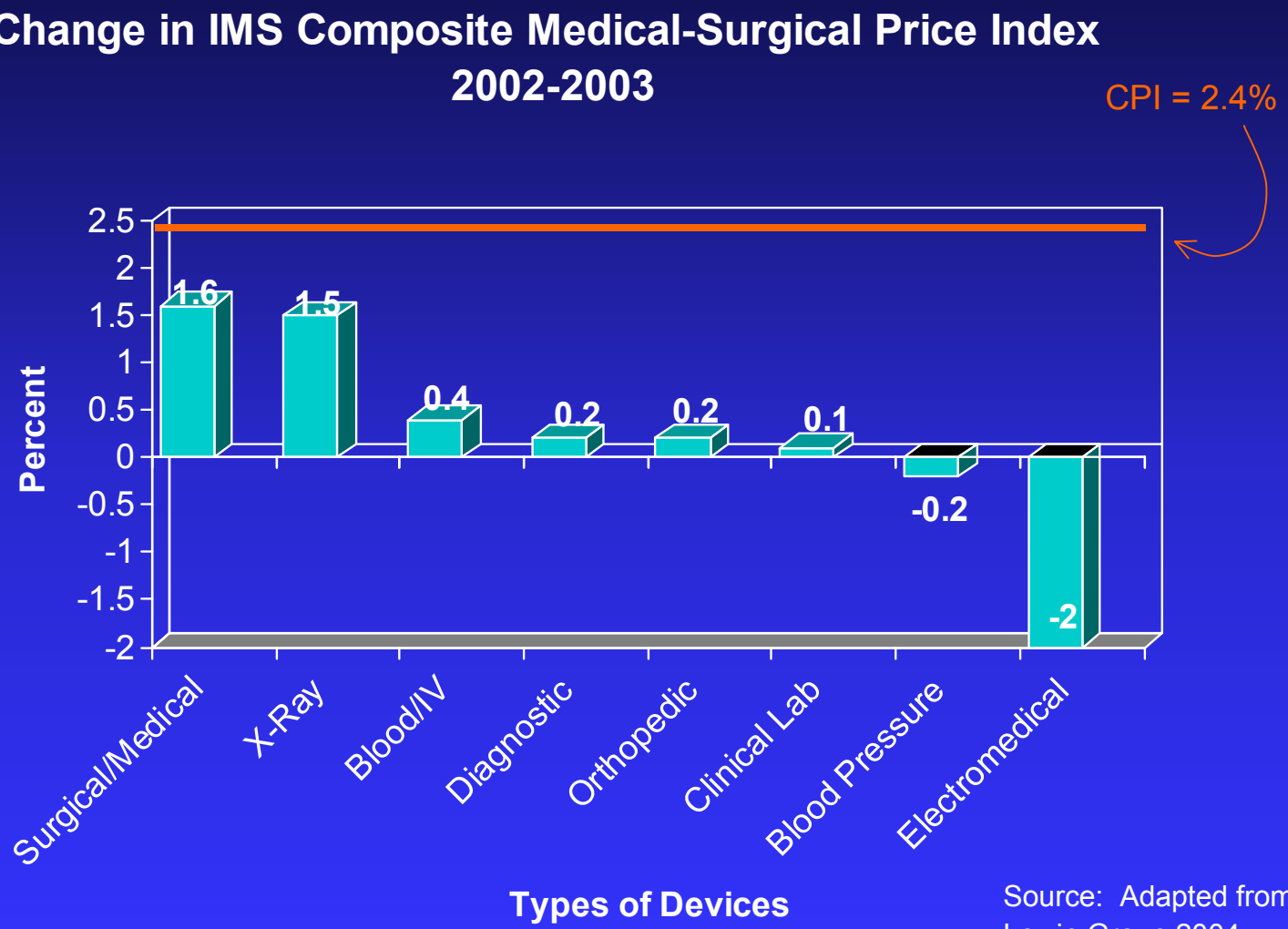
Companies Rely on New Products

"Half of our sales revenue during the past four years was derived from products less than one year old." 2003

"…About two-thirds of [our] current revenues are generated from products and therapies introduced within the last two years. 2004

Device Prices

Often below inflation or dropping

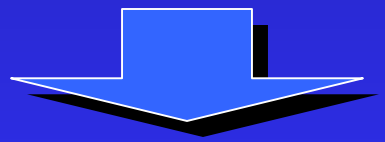


Source: Adapted from Lewin Group 2004

Overall Value of Investment

Since ‘80, per capita expenses up $2,254, but:

- Overall death rate down 16%
- Life expectancy up 3.2 years
- Disability rates down 25% for over 65
- 25% fewer days are spent in the hospital

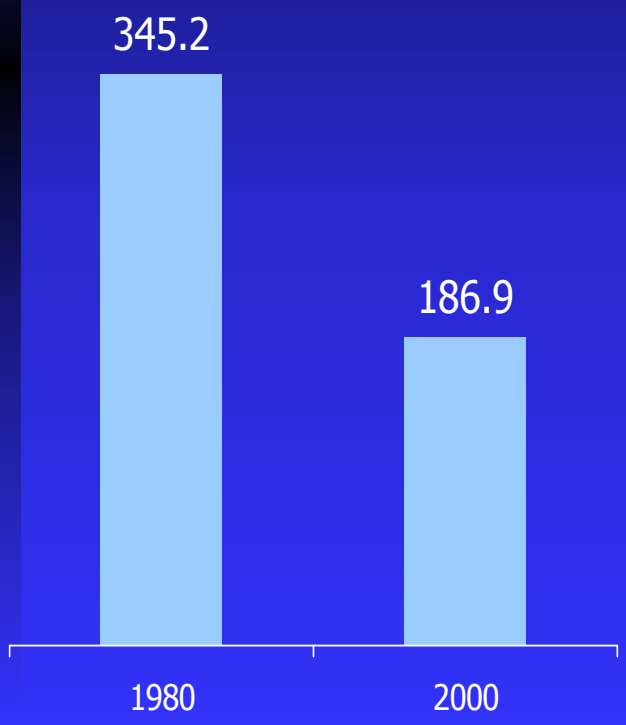


Health gains of $2.40 to $3.00 per dollar invested

Medtap 2004

Heart Attack:
Mortality reduced, hospital stays down

Death Rate Due to Heart Attack
(Age-adjusted, per 100,000)

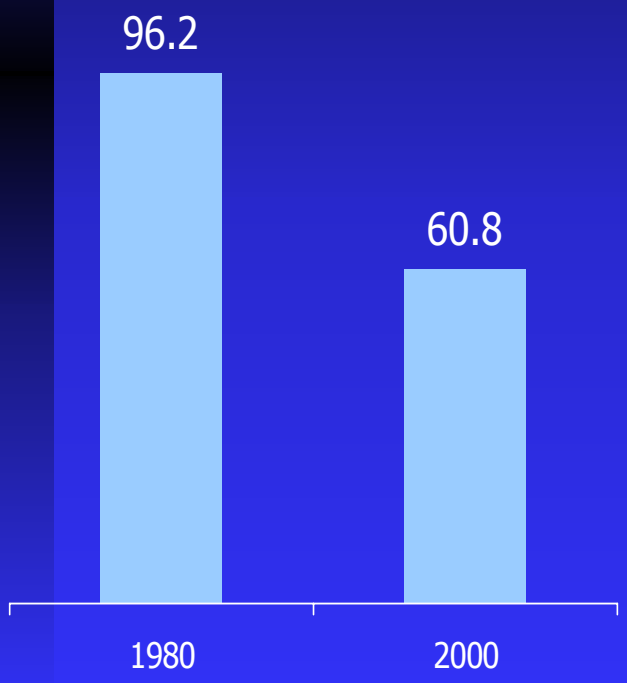


- Mortality cut ≈ 50%
- Death in 30 days: cut from 1 in 4… to 1 in 8
- Hospital stays: from 3-4 *weeks* …to 5-7 *days*

Medtap 2004

Stroke:
Faster detection, less disability

Death Rate Due to Stroke
(Age-adjusted, per 100,000)

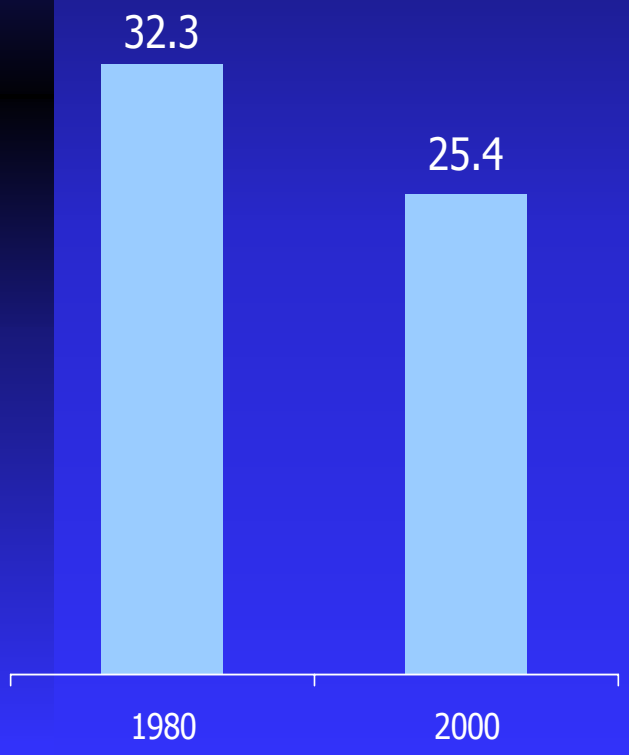


- Mortality cut 37 %
- Stroke-related disability reduced by up to 30%
- Faster diagnosis

Medtap 2004

Breast Cancer:
Better detection, therapy; lives saved

Death Rate Due to Breast Cancer
(Age-adjusted, per 100,000)

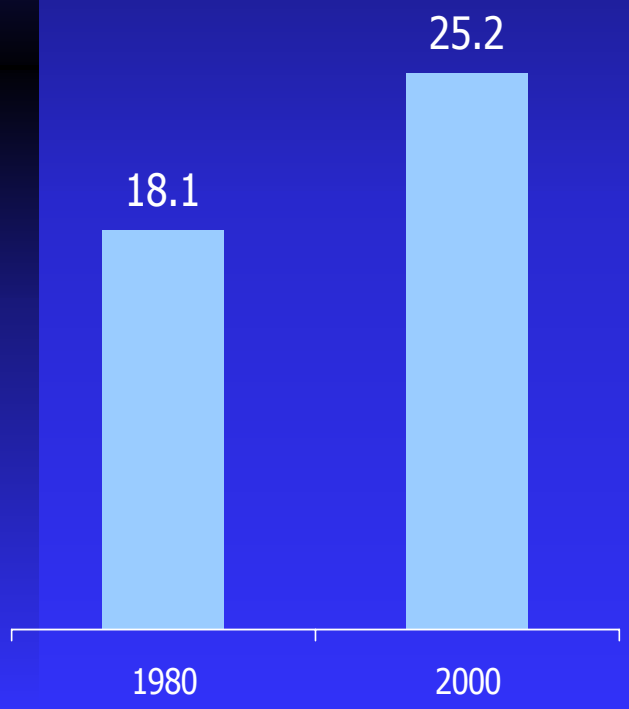


- Mortality cut 21%
- 5-year overall survival rates increased from 77% to 87%
- Risk of developing metastatic disease declined from 40% to 15%

Medtap 2004

Type 2 Diabetes:
Better detection, control

Death Rate Due to Diabetes
(Age-adjusted, per 100,000)



- Mortality increased, obesity rates doubled
- When glucose controlled, mortality decreases 10%, eye disease by 25%
- When blood pressure is controlled, mortality decreases 32%, eye disease by 37%

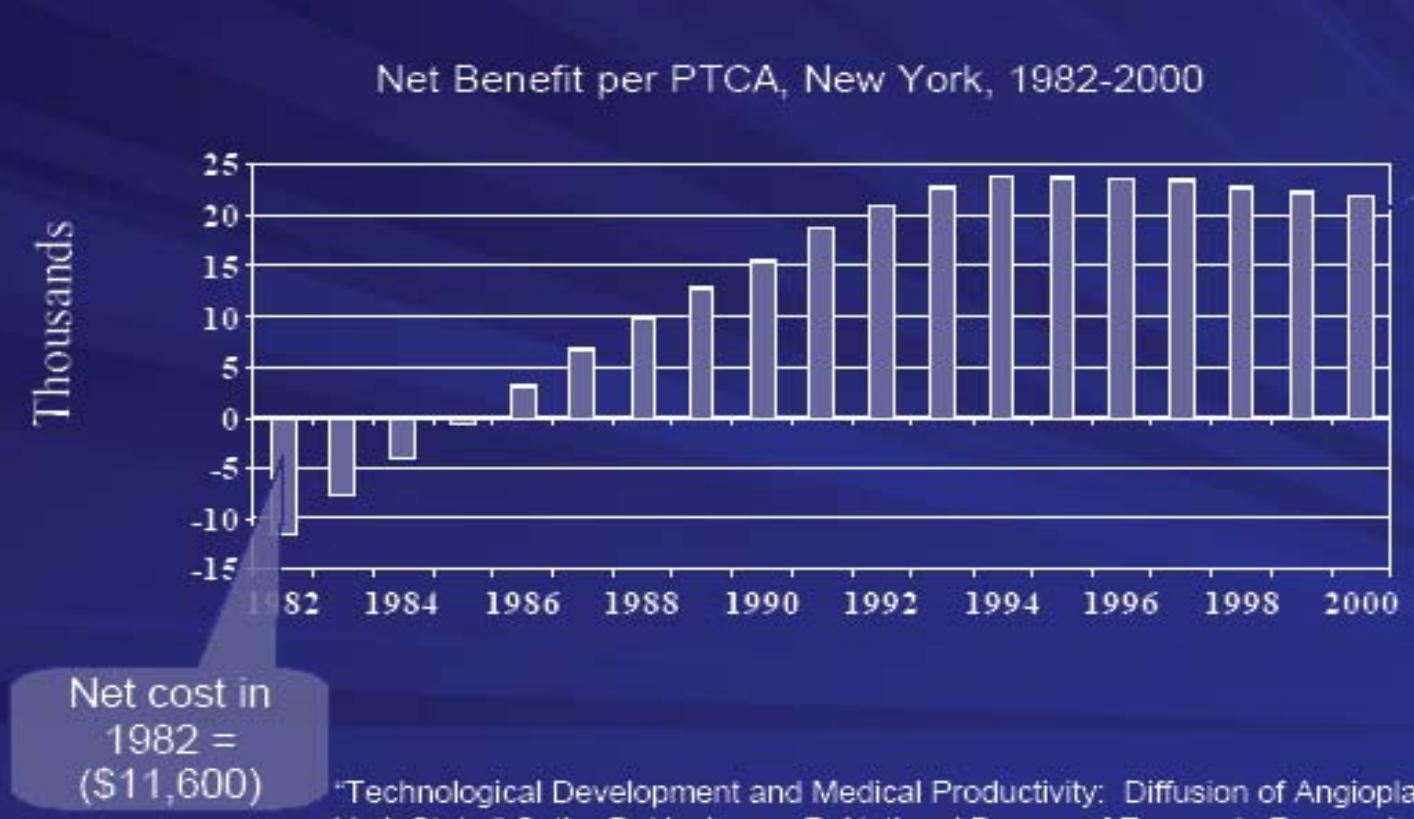
Medtap 2004

Role of medical devices…

Breast Cancer	• Mammograms • Image-guided breast biopsy • Minimally invasive surgery
Stroke	• MRI, CT exams • Coils for brain aneurysms • Carotid endarterectomy
Heart Attack	• Coronary angioplasty • Angiography • Defibrillators • Stents
Diabetes	• Hemoglobin A1c tests • Home glucose tests

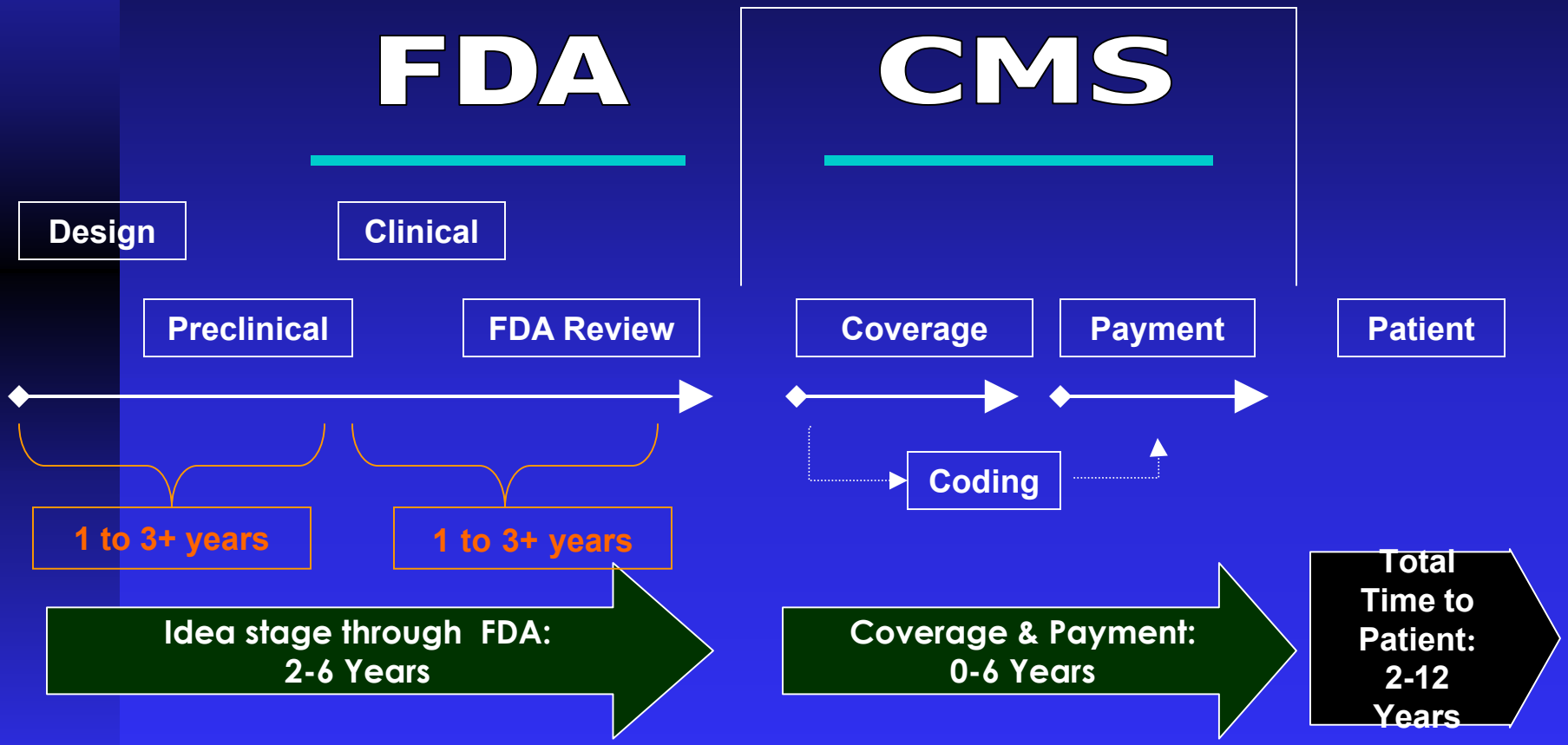
Source: MedTAP, 2004

Angioplasty reduces angina, opens blockages



"Technological Development and Medical Productivity: Diffusion of Angioplasty in New York State," Cutler D, Huckman, R; National Bureau of Economic Research, Oct 2002

Device Innovation:
From FDA through Medicare



Source: Lewin Group, 2000, 2004

Working with FDA to Shorten Device Review and Development Times

- User Fees
- Performance Standards
- Critical Path Analysis

Working with Medicare to Speed Coverage and Payment

- Coding Reform
- New Methods of Paying for New Technology
- “Charge Compression”

Concern About Costs Presents New Challenges

- Declining Insurance Coverage
- Paying for Performance
- Rebasing DRGs
- Cutting Cost and Ignoring Value
  - Comparing Resource Use by Physicians
  - Imaging