National Venture Capital Association

FDA Stakeholder Meeting On Implementation of MDUFMA Review Performance Goals

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Overview

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- Role of venture capital in medical device innovation

- NVCA's recommendations on MDUFMA Performance Goals
  - Provide a streamlined pathway for the commercialization of medical technologies for quicker patient to access to innovative medical technologies
    - Save and improve the lives of patients
    - Help drive down the cost of health care expenditures

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Role of Venture Capital in Medical Device Innovation

What Does A Venture Capitalist Do?

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- We Create New Companies, Often Based on Revolutionary Technologies
  - High Tech
  - Medical
- We Provide Capital for the Earliest Stages of Start-Up Companies
- Board Directors and Corporate Officers
- Most of Us Have Been Entrepreneurs or Technologists Ourselves

The U.S. Venture Capital Industry

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The NVCA Represents:

- 465 Venture Capital Firms in U.S.
- 90% of All U.S. Venture Capital Under Management

At Year End	# Venture Firms	Capital Under Management
1970	28	$1B
1980	89	$4B
1990	398	$31B
2000	887	$223B
2004	897	$261B

VC Industry Remains an Institutional Asset Class

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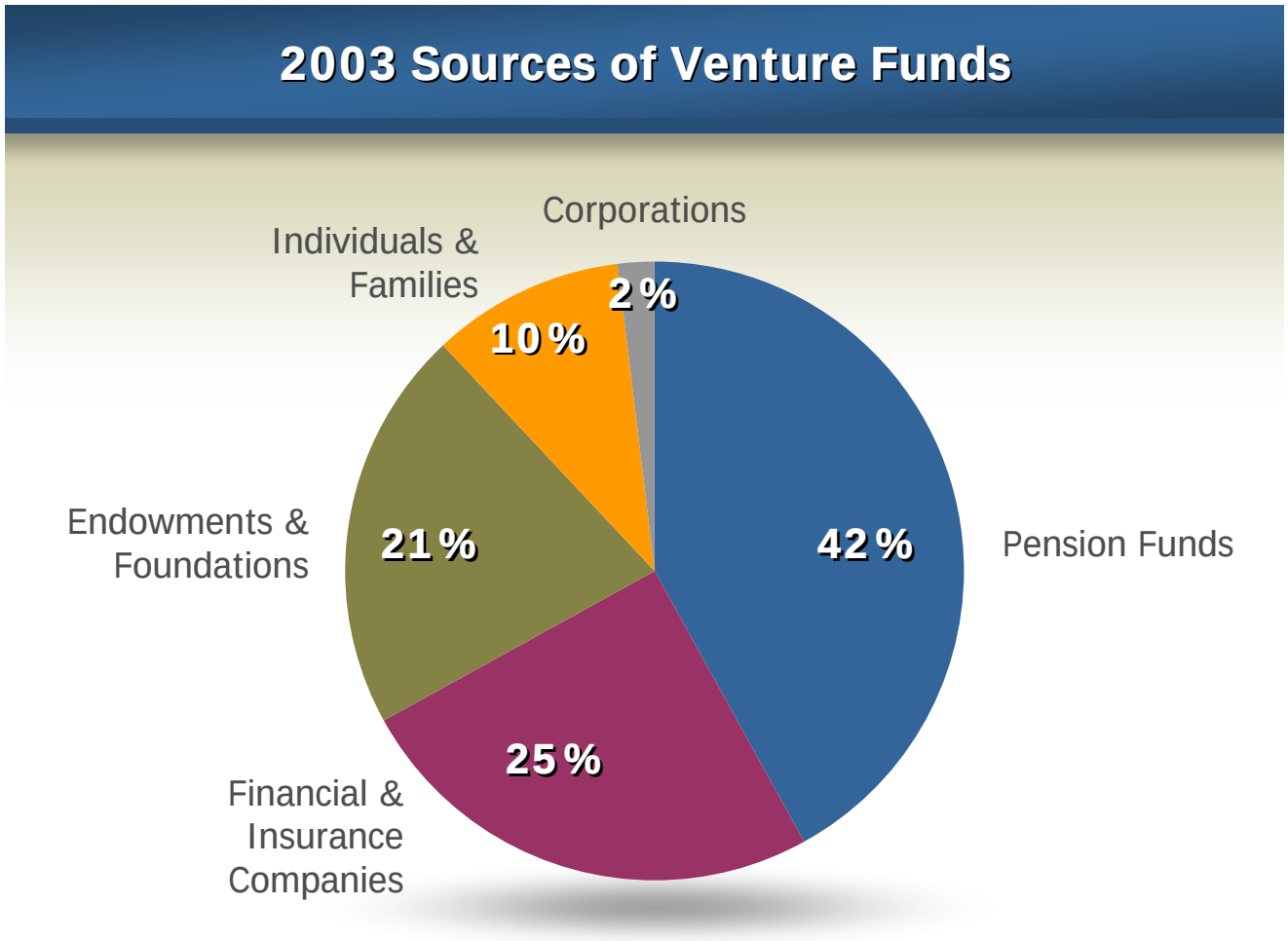

Source: 2003 data from 2004 NVCA Yearbook, prepared by Venture Economics, page 22

U.S. Venture Capital Contribution to the U.S. Economy

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- Venture-Backed Companies Represent 10% of The U.S. Economy in 2003:
  - 10.1 Million U.S. Jobs
  - $1.8 Trillion of U.S. GDP
- Between 2000 and 2003, Venture Backed Company Employment Grew Employees 6.5% While U.S. Private Sector Jobs were Down 2.3%
- Venture-Backed Companies Represented More Than 40% of All IPOs Between 1970 and 2003
- Venture Backed Companies Spend More Than Twice as Much on R&D as Non-venture Companies

VC Investing: 1998 to 2004
Life Science Investing Up Almost 2x

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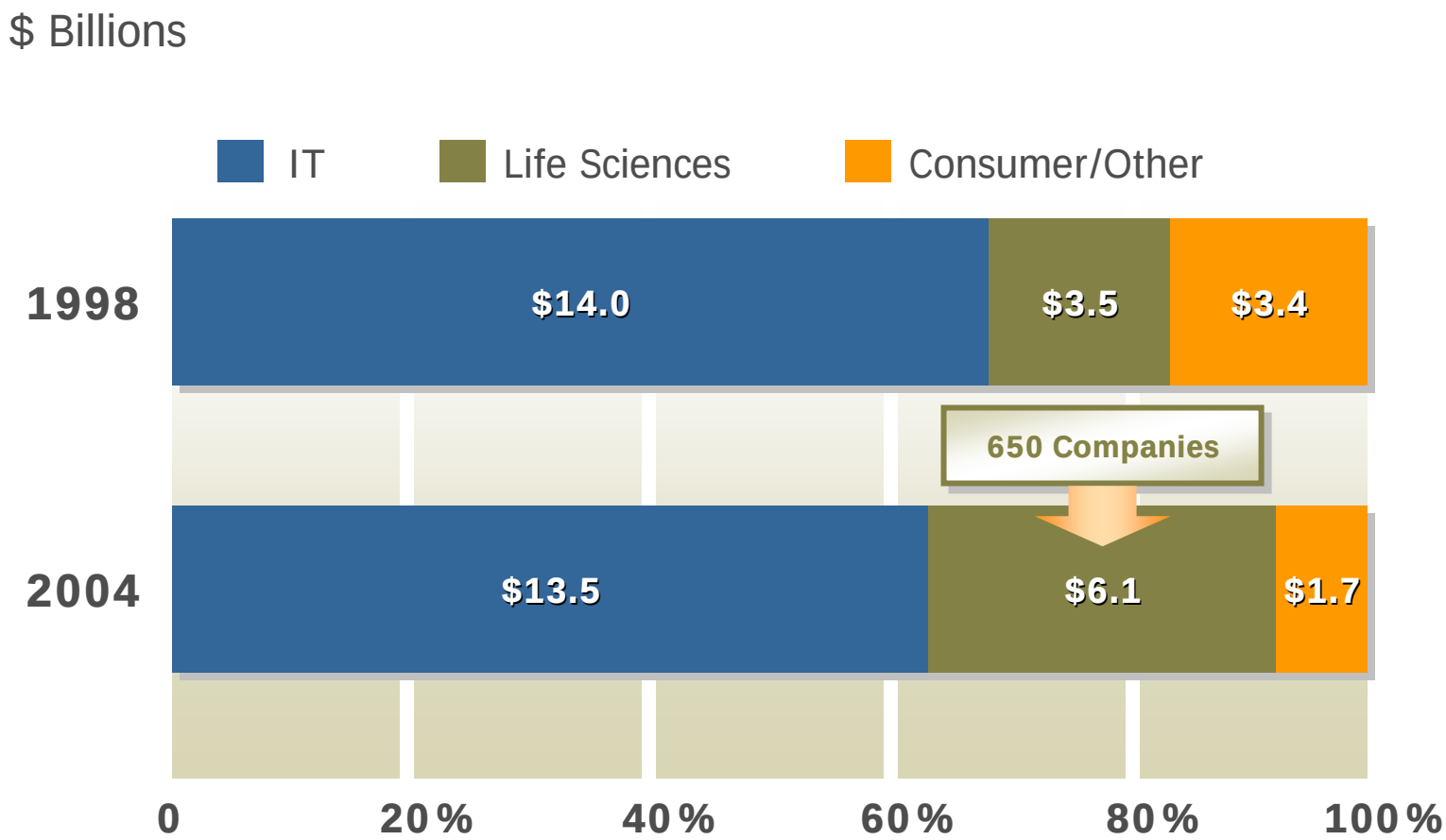

Source: PricewaterhouseCoopers/Venture Economics/National Venture Capital Association MoneyTree™

Patient Capital

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- Venture capital plays a vital role in life science innovation
  - Many innovations have revolutionized the practice of medicine
- Over 100 million Americans have been positively affected by venture backed medical innovations
- Venture capital combats American's leading causes of death
- Venture capital backed life sciences companies contribute to the U.S. economy

Focused on Start-Ups and R&D

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Average Med Tech VC Investment Per Company	Targeted Spend
$30-60M	Operations, Sales, Marketing, Research and Development

= Innovation

Source: NVCA Money Tree

Venture Investing Drives Revolutionary, Life Saving Innovation

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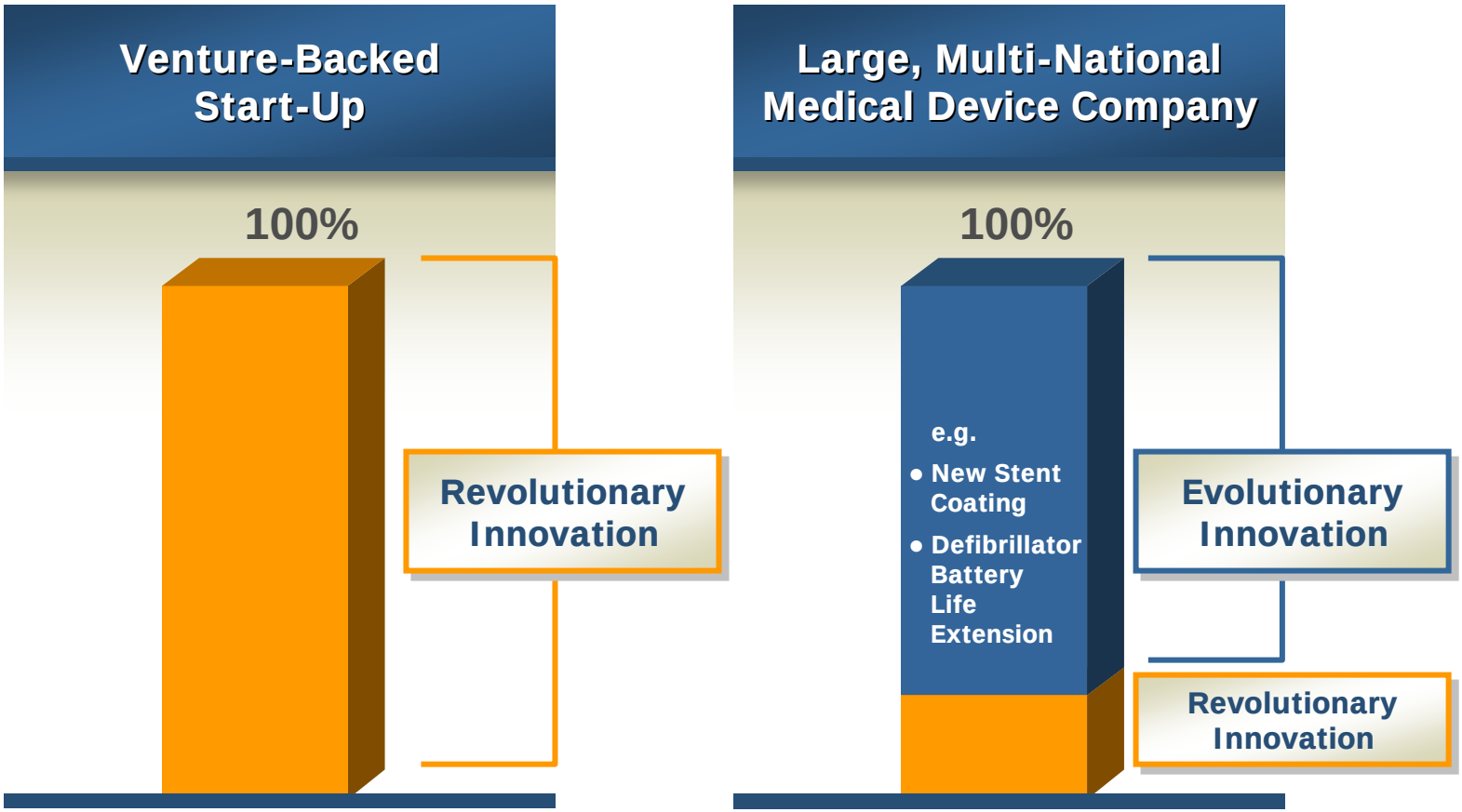

The Revolutionary Innovations of Venture-Backed Medical Device Start-Ups

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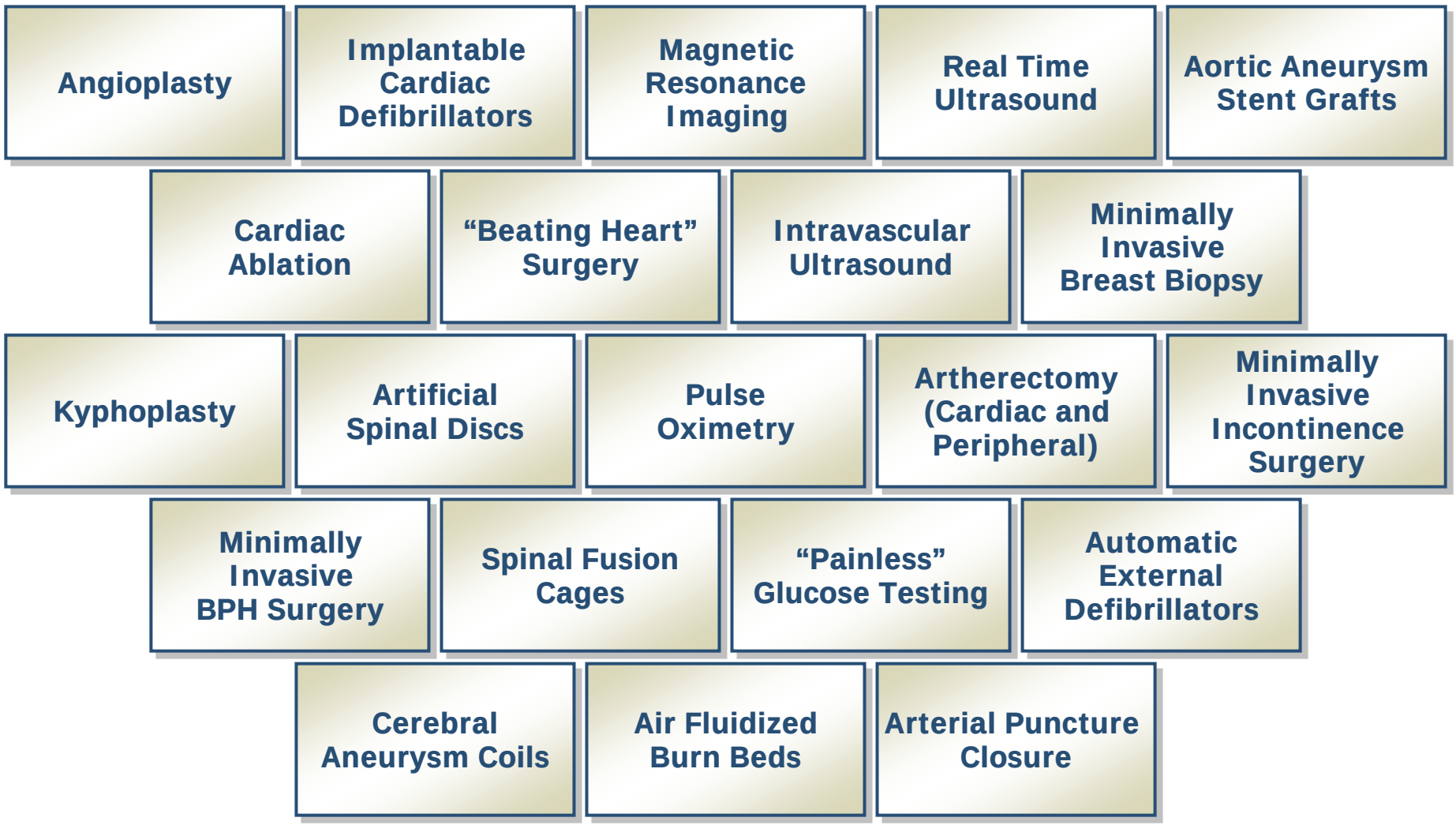

Current Medical Device VC Investment Focus

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Project	Companies
Spinal Nucleus Replacements	>15
Dynamic Spine Stabilization	>15
Intervention Treatment of Peripheral Atherosclerosis	>15
Biodegradeable or Novel Stents	>15
Neurostimulation (Pain, Epilepsy, Depression)	>10
PFO Closure	>10
Vulnerable Plaque	>10
Cartilage Repair	>10
Stabilization of Heart Failure	>10
Interventions for AMI	>10
Interventions for Acute Stroke	> 5
3rd Generation AAA Gaffs	> 5
Artificial Retinas	> 5
3rd Generation LVADs	> 5
Acute Interventions for DVTs	> 5

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Points to Consider | MDUFMA Performance Goals

FY2007 MDUFMA Performance Goals

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- **PMA Decision Goals**
  - *(a) 80% of submissions received in fiscal year 2006 will have an FDA decision in 320 days*
  - *(b) 90% of submissions received in fiscal year 2007 will have an FDA decision in 320 days*
  - **(c) 50% of submissions received in fiscal year 2007 will have an FDA decision in 180 days**
- **510(k) Decision Goals**
  - *(a) 75% of submissions received in fiscal years 2005 and 2006 will have an FDA decision in 90 days*
  - **(b) 80% of submissions received in fiscal year 2007 will have an FDA decision in 90 days**

CDRH Performance

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- FDA has met most MDUFMA performance goals (GAO 9.05) and will likely continue to meet or exceed future, modest goals
- But such goals only marginally improve the time to market of PMAs and 510(k)s-and do not substantially accelerate the availability of novel technology or foster innovation
- Accelerating the commercialization of novel technology improves health outcomes and can reduce expenditures

Key Considerations

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- Novel technology submissions deserve particular attention and may be an appropriate focus for revised MDUFMA performance goals and fees
- CDRH should not meet 510(k) performance goals through the increased issuance of NSE decisions
- Review cycle goals and shorter timeframes for later review cycles would encourage collaboration and earlier resolution of issues

"Novel Technology"

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- **Novel technology is a small but vital subset of total annual submissions, and poses a special challenge:**
  - **To CDRH staff and advisory committees who may lack clinical and regulatory experience**
  - **In designing and executing appropriate clinical trials**
- **Policies to improve the review of novel technology could include:**
  - **Earlier participation by senior CDRH officials**
  - **Involvement of outside experts**
  - **Explicit, ambitious meeting management and goals**
  - **Flexibility in advisory panel composition**
  - **Greater flexibility in trial design**
  - **Reduced cycle times**

FDA Regulation: Trends and Consequences

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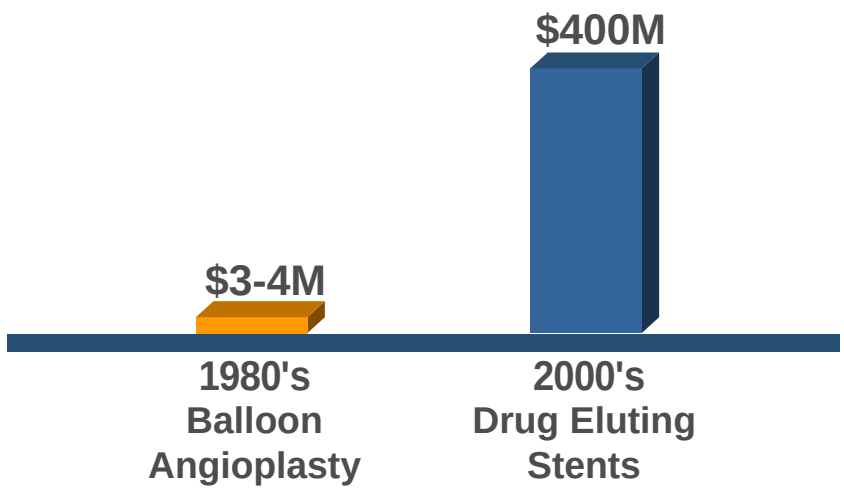
Trends

- Technology More Complex
- FDA More Conservative
- Increasing Restrictions

Consequences

- Regulatory Path More Difficult
- More Unpredictable
- And Much More Costly …



Summary

FDA can help commercialize novel technologies more timely and help drive down health care expenditures

- Provide a clear approval pathway for innovative technologies
- Meet 510(k) performance goals with more timely reviews instead of increased issuance of NSE decisions
- Early resolution of issues and greater collaboration and would shorten review cycles and approval timeframes