



National Venture Capital Association

**FDA Stakeholder Meeting
On Implementation of
MDUFMA Review Performance Goals**

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1



National Venture Capital Association

Overview

- 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

2

Role of Venture Capital in Medical Device Innovation

3

What Does A Venture Capitalist Do?

- 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

4

The U.S. Venture Capital Industry



The NVCA Represents:

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

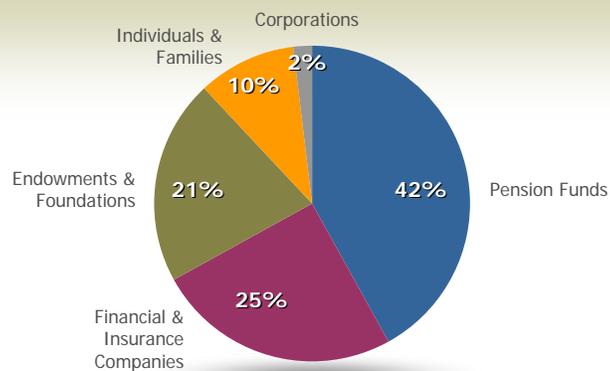
At Year End	# Venture Firms	Capital Under Management
1970	28	\$1B
1980	89	\$4B
1990	398	\$31B
2000	887	\$223B
2004	897	\$261B

5

VC Industry Remains an Institutional Asset Class



2003 Sources of Venture Funds



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

6

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



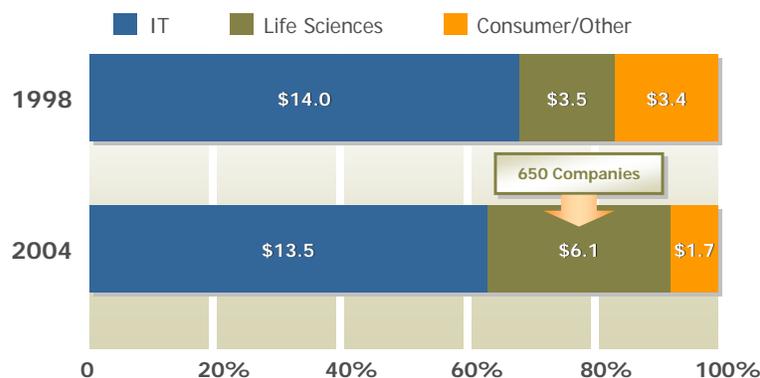
- Venture-Backed Companies Represent 10% of The U.S. Economy in 2003:
 - 10.1 Million U.S. Jobs
 - \$1.8 Trillion of U.S. GDP
- Between 2000 and 2003, Venture Backed Company Employment Grew Employees 6.5% While U.S. Private Sector Jobs were Down 2.3%
- Venture-Backed Companies Represented More Than 40%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

7

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



\$ Billions



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

8

Patient Capital

- 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

9

Focused on Start-Ups and R&D

Average Med Tech
VC Investment
Per Company

\$30-60M

Targeted Spend



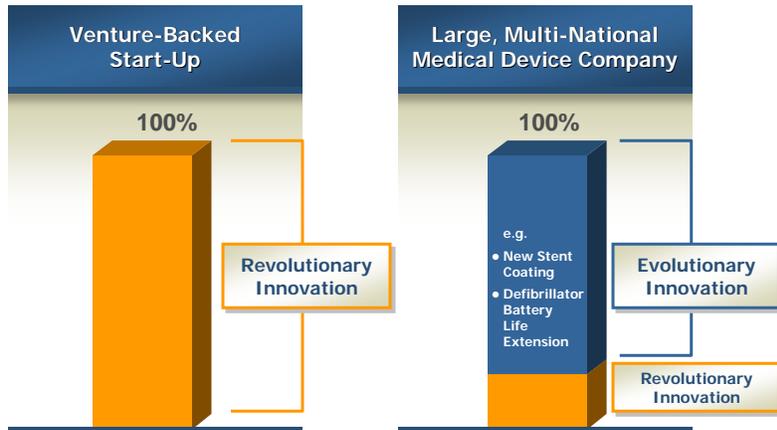
Research and
Development

= Innovation

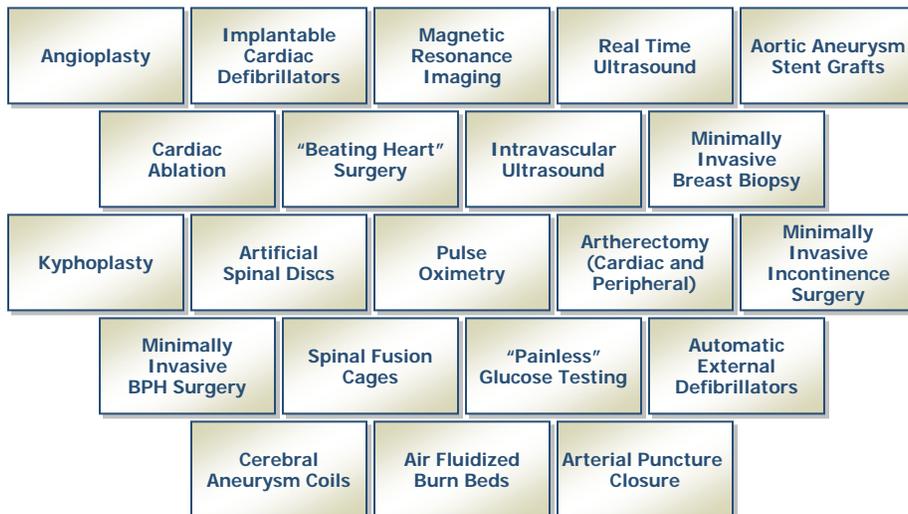
Source: NVCA Money Tree

10

Venture Investing Drives Revolutionary, Life Saving Innovation



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



Current Medical Device VC Investment Focus



Project	Companies
Spinal Nucleus Replacements	> 15
Dynamic Spine Stabilization	> 15
Intervention Treatment of Peripheral Atherosclerosis	> 15
Biodegradable 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 Grafts	> 5
Artificial Retinas	> 5
3rd Generation LVADs	> 5
Acute Interventions for DVTs	> 5

13



Points to Consider | MDUFMA Performance Goals

14

FY2007 MDUFMA Performance Goals



- **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**

15

CDRH Performance



- 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

16

Key Considerations

- 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

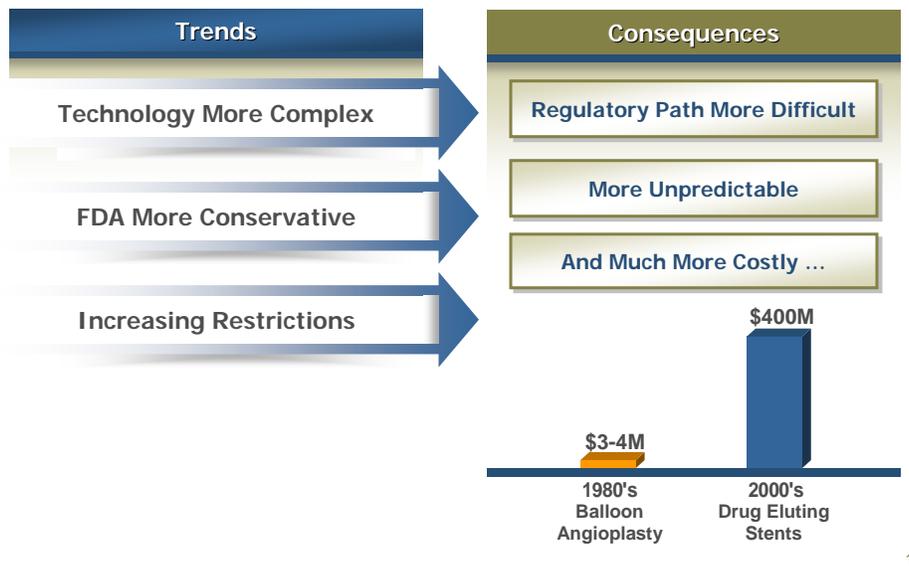
17

"Novel Technology"

- 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

18

FDA Regulation: Trends and Consequences



19

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

20