



National Venture Capital Association

MDUFMA Reauthorization: Key Issues For Venture Capital

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Vertical Group

Venture Capital Improves the Lives of Millions

OVER 100 MILLION AMERICANS

have been positively affected by venture-backed medical innovations developed during the past 20 years

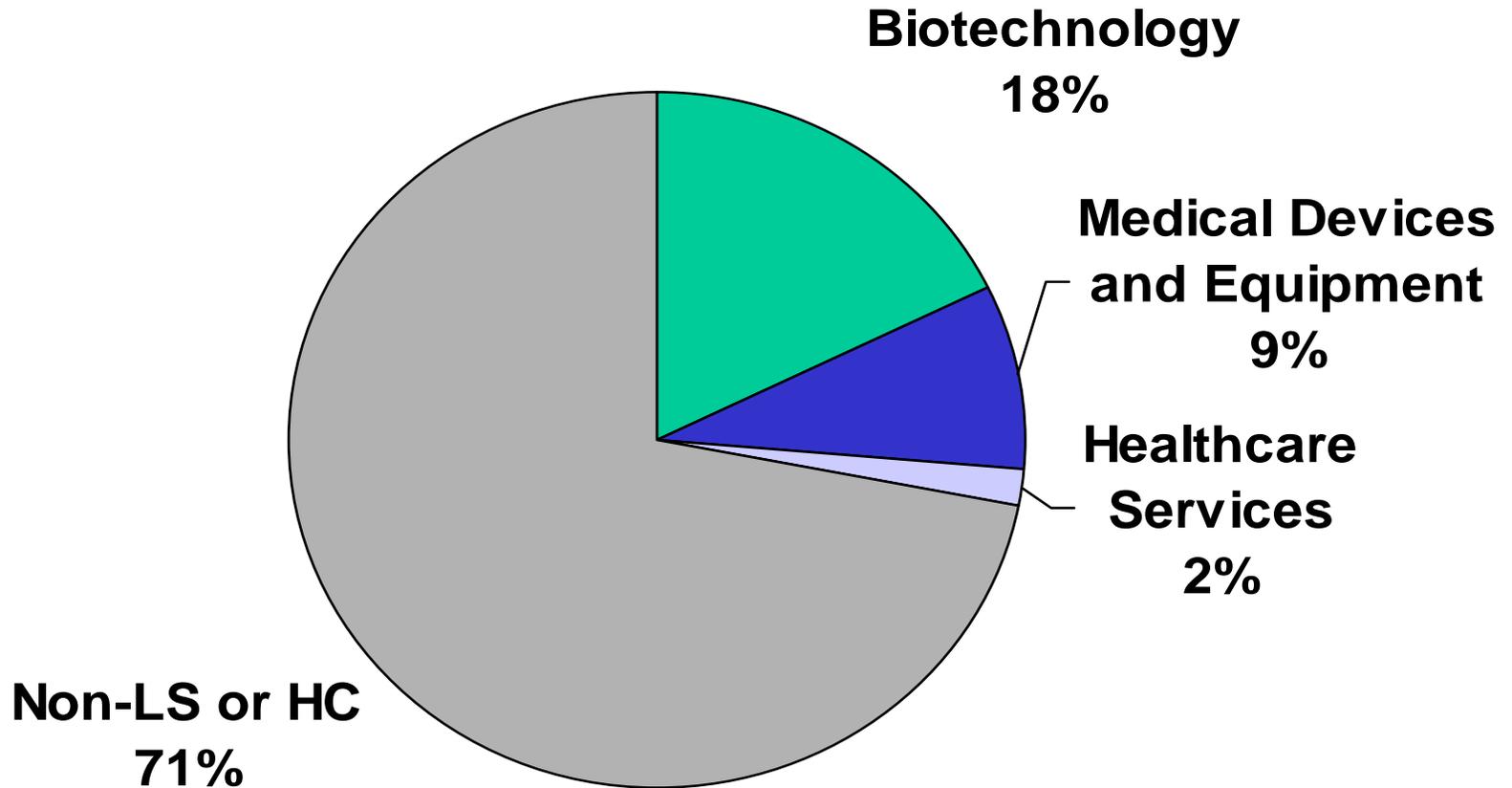
OVER 25 MILLION AMERICANS

have their life extended or quality of life improved every year, through the use of venture-backed diagnostic and therapeutic products

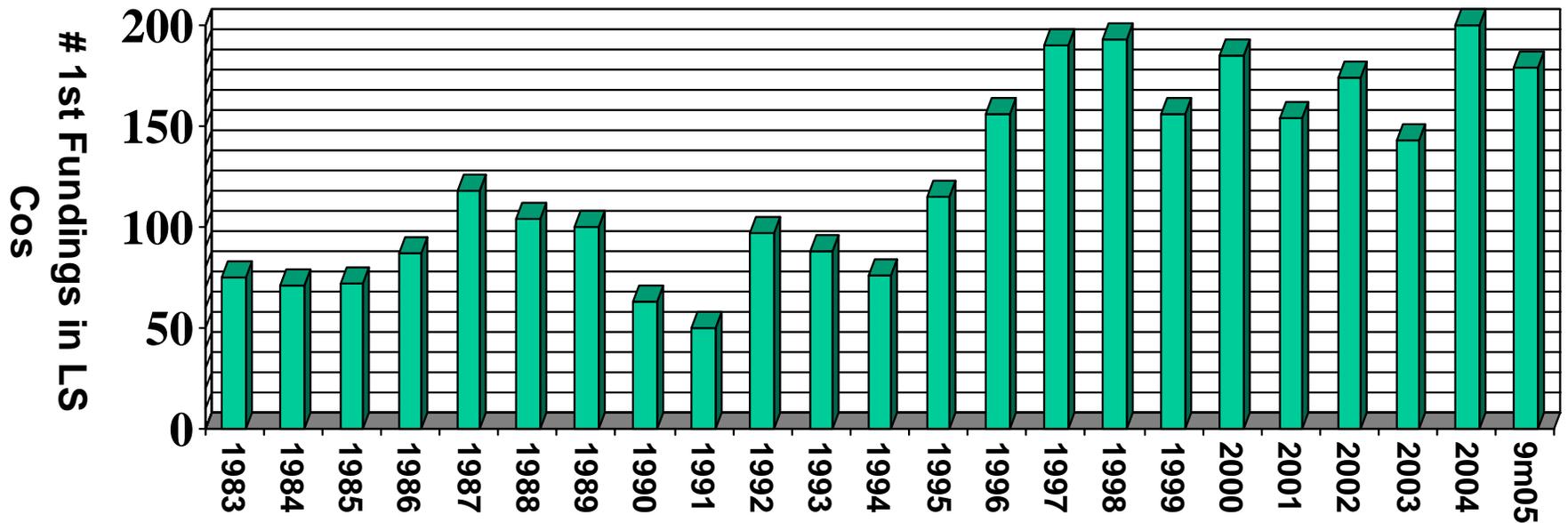
Venture Capital Combats America's Leading Causes of Death

Cause of Death	Deaths (2001)	Venture Capital Support (20 years)	Venture Backed Innovative Treatments
Heart Disease	700,142	\$22 billion	angioplasty, minimally invasive coronary bypass, electroablation, implantable cardioverter-defibrillators (ICD's), automated external defibrillators (AED's) Integrilin, ReoPro
Cancer	553,768	\$9 billion	doppler ultrasound, minimally invasive biopsy, PSA, MRI, Avastin, Erbitux, Velcade, Gliadel, Herceptin, Rituxan
Stroke	163,538	\$1.3 billion	MRI, TPA
Respiratory Disease	123,013	\$19.5 billion	FluMist, mechanical ventilators, pulse oximetry

Life Sciences and Healthcare Services YTD Make Up Almost 1/3 of Total Venture Investment



Number of First Financings for LS Companies Remains Strong

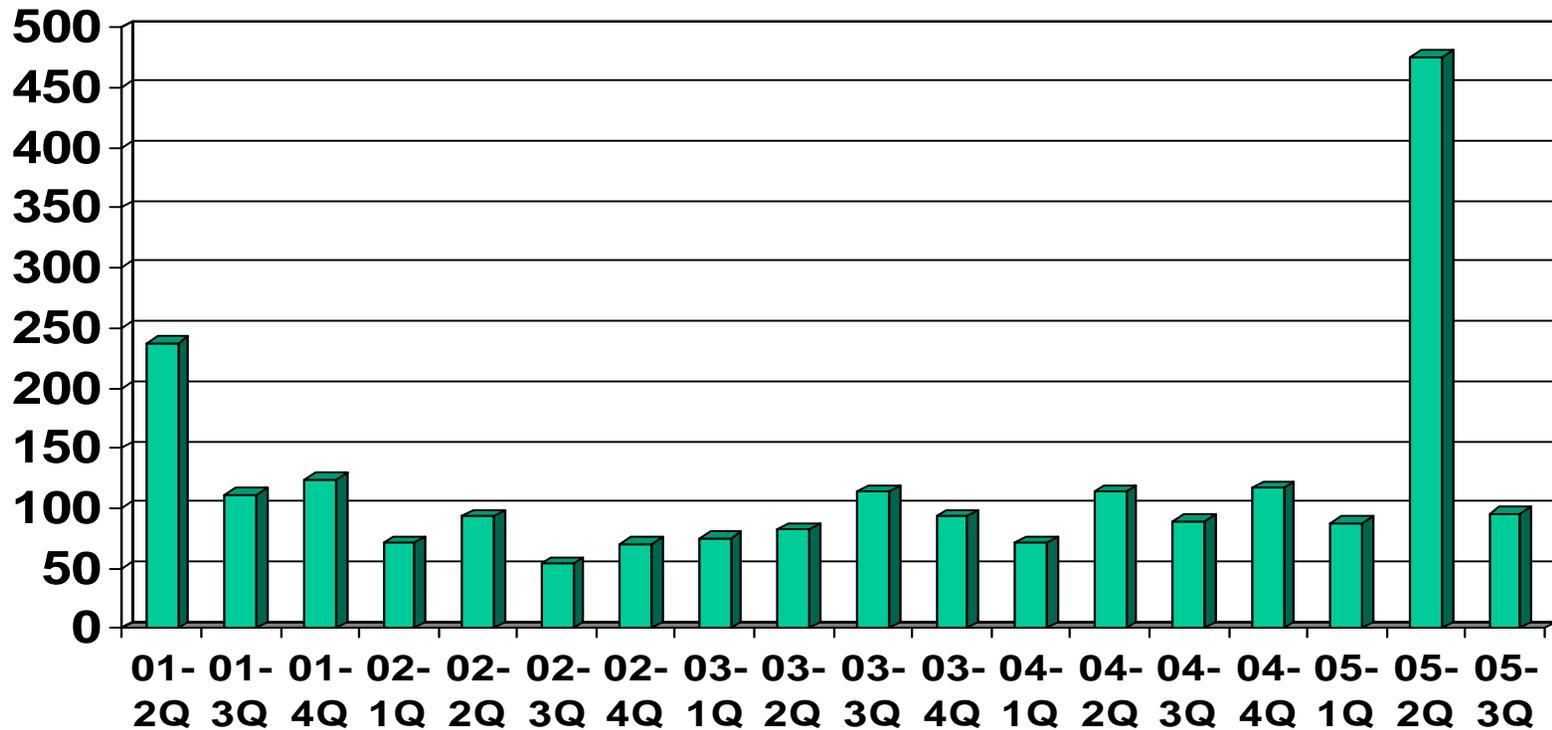


Source: PricewaterhouseCoopers/Venture Economics/National Venture Capital Association MoneyTree™

Medical Device Startups

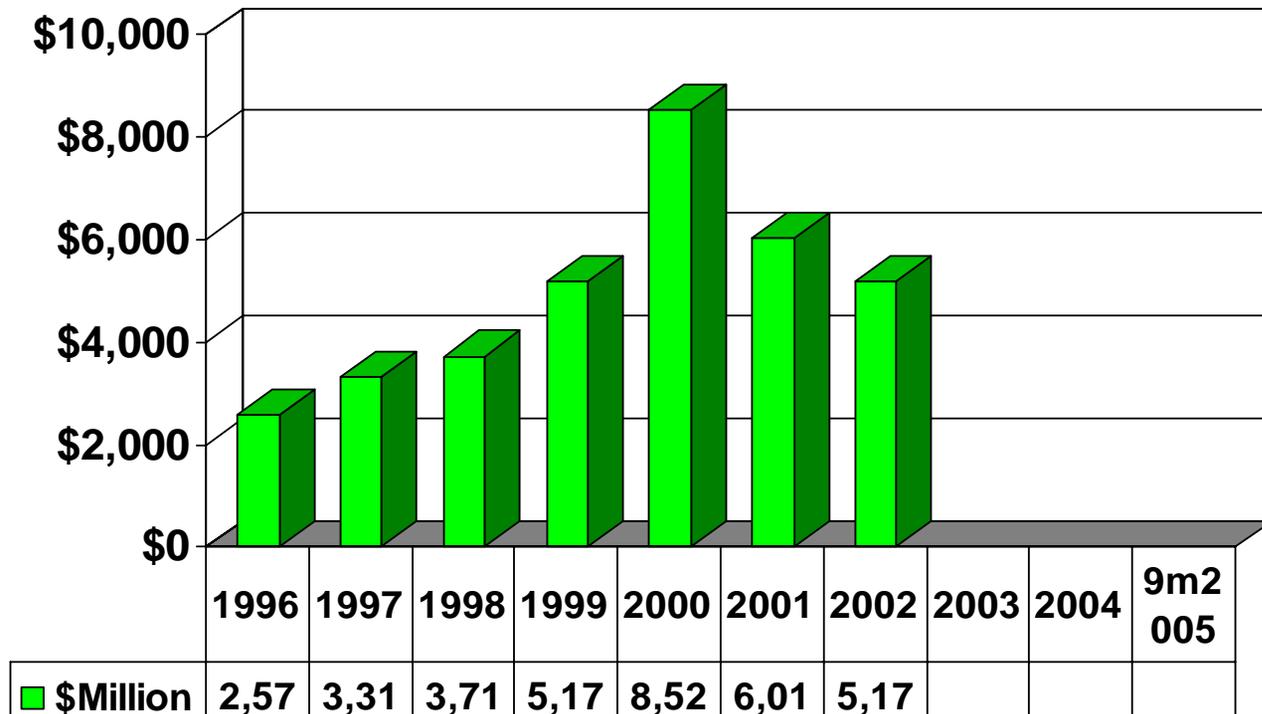
First Financings for Medical Device Companies

Millions



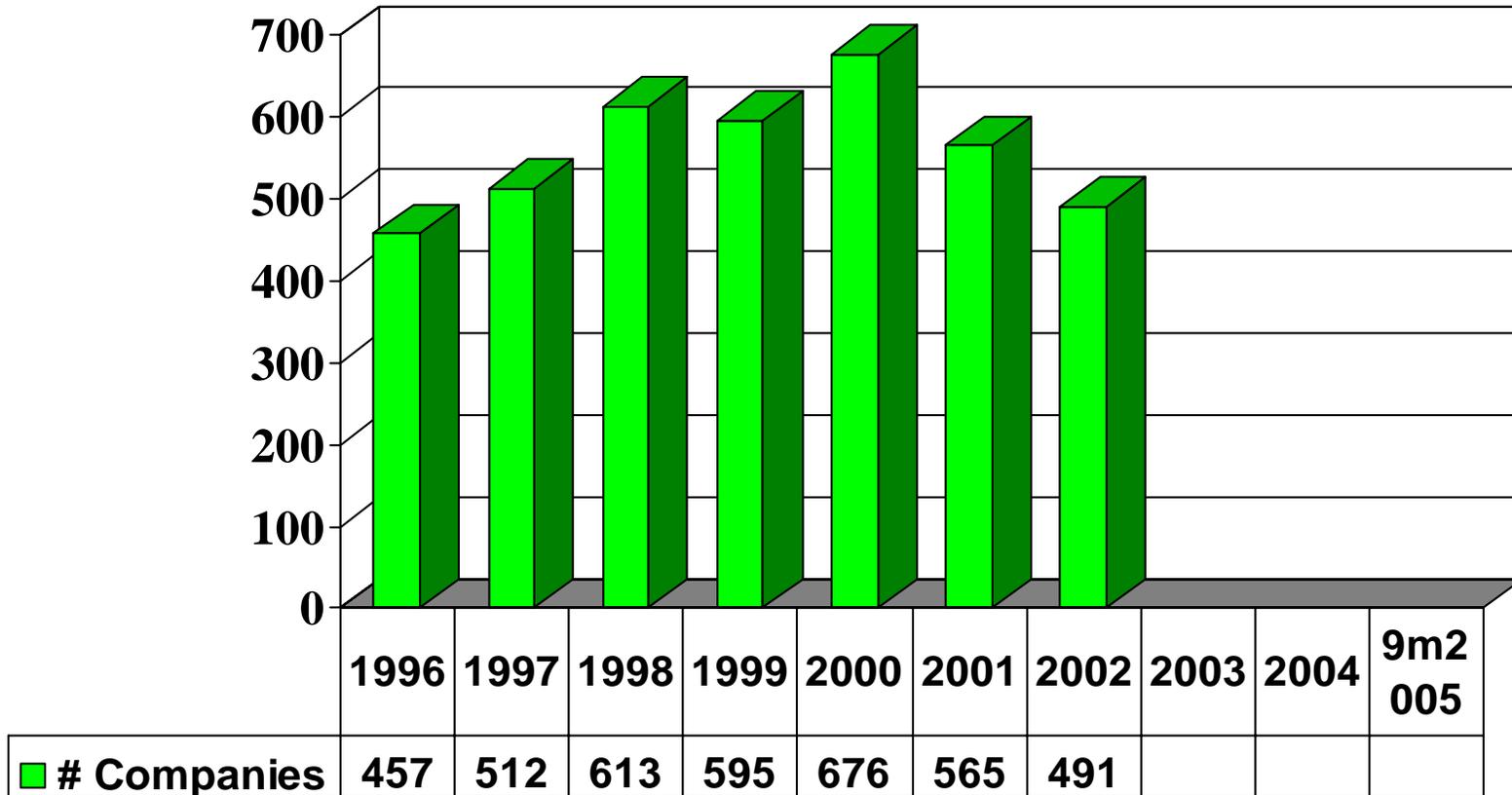
Source: PricewaterhouseCoopers/Venture Economics/National Venture Capital Association MoneyTree™

Total Life Science Investment Is Much Greater than Pre-2000 Levels



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

Number of LS Companies Receiving Funding Is Steady

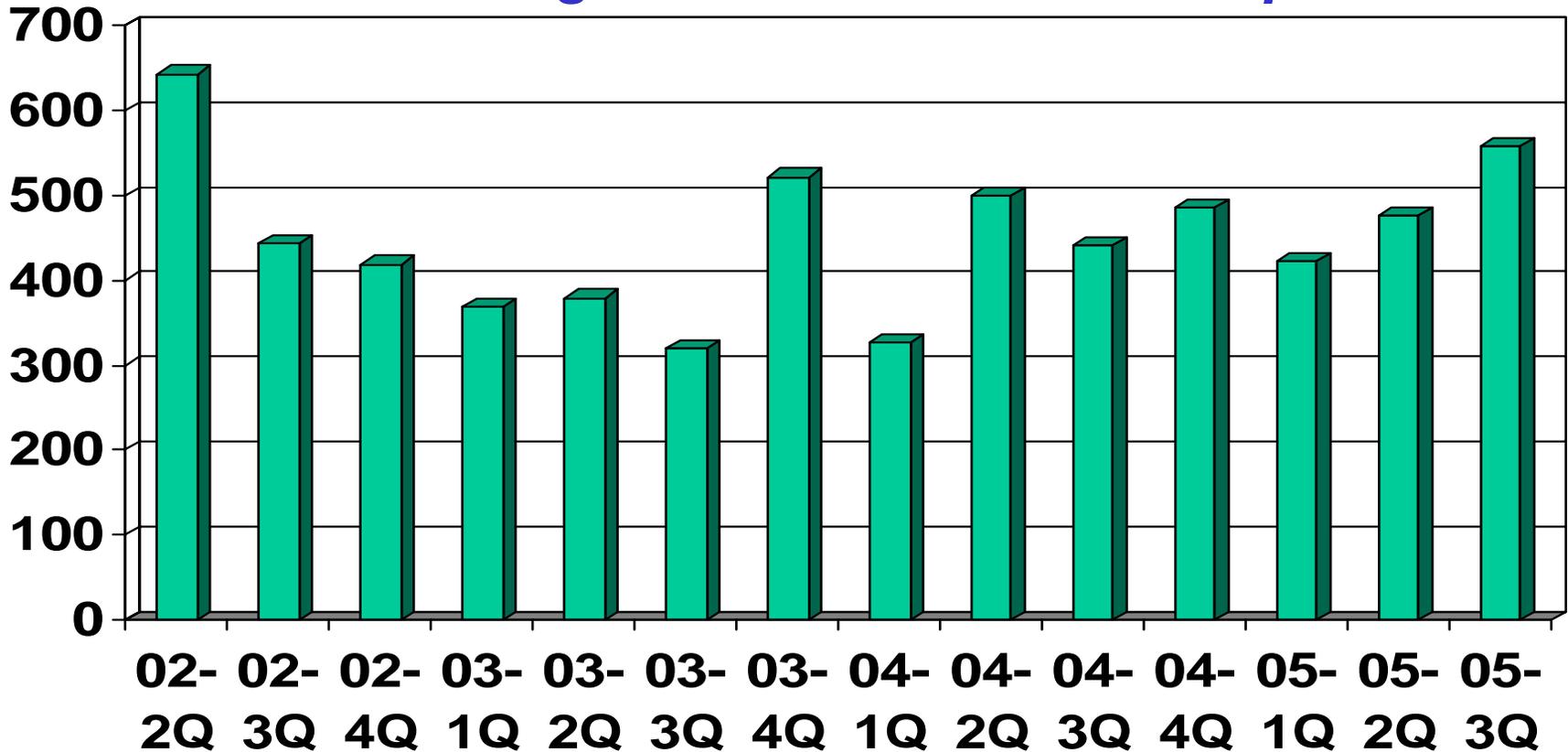


Source: PricewaterhouseCoopers/Venture Economics/National Venture Capital Association MoneyTree™

Medical Device Industry Remains Strong

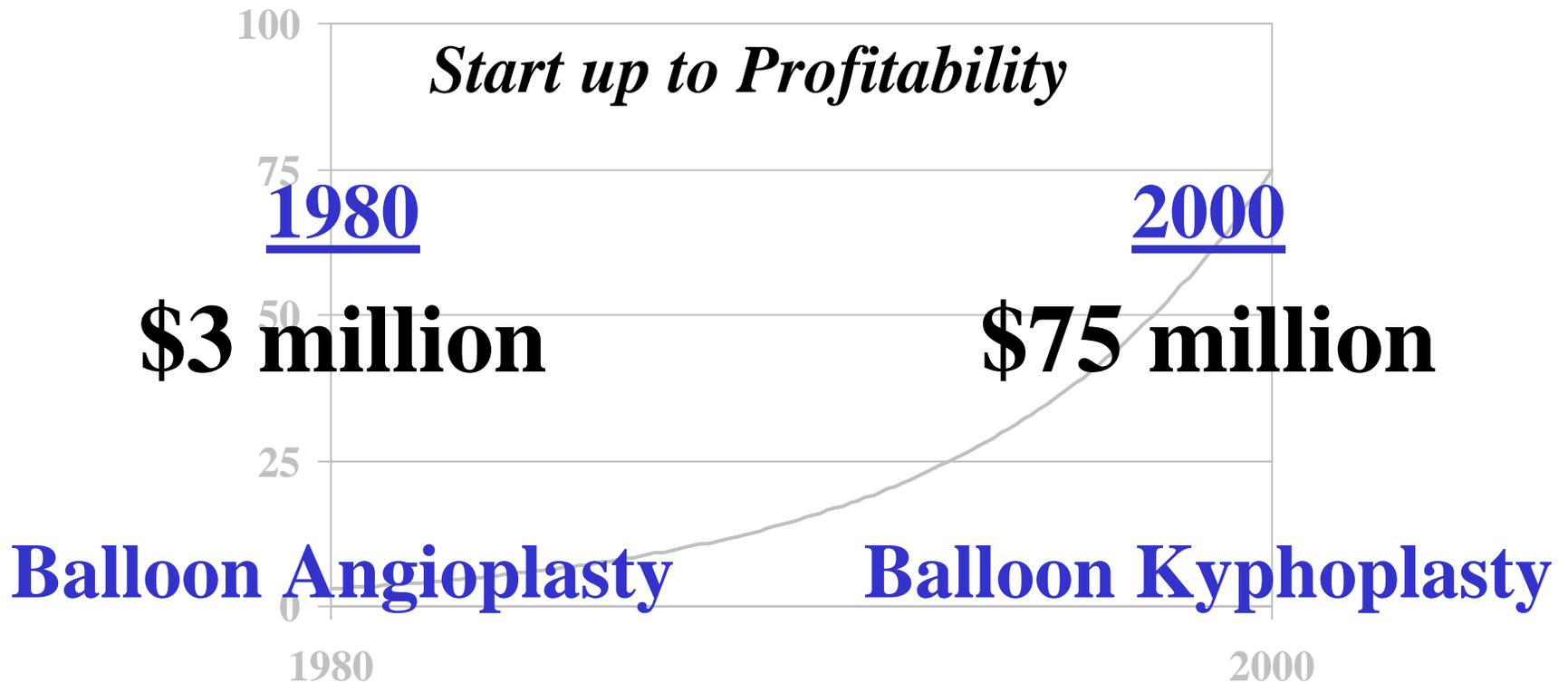
VC Funding for Medical Device Companies

Millions



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

Funding Requirements for Medical Devices



VC Funded Medical Devices

Revolutionary, *Not Evolutionary*

Angioplasty

MRI

Pulse oximetry

Cardiac ablation

ICDs

AAA Stent Grafts

Beating Heart Surgery

Disc Arthroplasty

Kyphoplasty

Neurostimulation

Novelty Creates Unique Regulatory Challenges

- **Education of CDRH Staff**
- **Lack of Precedents and Pathways**
- **Clinical Trial Design and Interpretation**

What VCs Are Doing in 2005

<u>Project</u>	<u>Companies</u>
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

What VCs Are Doing in 2005

<u>Project</u>	<u>Companies</u>
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

Performance Goals and Funding

- Substantial additional improvements possible in the **timeliness, transparency and consistency** of product reviews without a substantial increase in fees
- Assuring **greater consistency, predictability and quality** in the review of expedited PMAs and modular PMAs to be of the greatest importance

Performance Goals and Funding

- FDA and sponsors should consider the potential for **modest, non-application fees** reflecting appropriate small business exemptions to **increase the stability** of MDUFMA funding and **decrease existing application fees**, as well as to better assure **greater consistency, predictability and quality** of premarket reviews

Achieving First Cycle Approvals and Clearances

- FDA must recommit to consistency and clarity in its **application of “least burdensome” principles** to reduce unnecessary regulatory burden
- Congress should consider the necessity of **additional statutory guidance** to advance timely patient access to innovative treatments while ensuring CDRH seeks and receives from sponsors the appropriate assurance of device safety and effectiveness

Achieving First Cycle Approvals and Clearances

- **Meeting management performance goals** with specific timeframes for determination and agreement meetings, informal pre-IDE meetings, pre-PMA meetings, pre-PMA filing meetings should be a critical feature of any future MDUFMA agreement
- Targeted strategies like **special protocol assessments (SPA)**, and **continuous marketing application (CMA)** demonstrations should be considered

COA and Postmarket Surveillance Studies

- **Sponsor compliance** with postmarket surveillance studies should be reported accurately. **CDRH reporting and oversight should be improved**
- FDA should **issue guidance and outreach** to IRBs to expedite approval and conduct of COA studies

HDEs and Pediatric Devices

- Reconsider restrictive HDE/HUD guidance requiring sponsors to demonstrate that devices cannot be used for any other **“medically plausible” subpopulations** other than the population intended to be treated under a HDE designation
- Statutory and regulatory changes needed to raise the **patient population cap** and to remove the **profit restriction** on HDE/HUDs
- **Reduce unnecessary burdens** and clarify **diversity of study designs** permissible to establish safety and effectiveness, as well as the different forms that “valid scientific evidence” may take, for pediatric populations

Critical Path Initiative

- As medical technology advances at an accelerating rate, the **Critical Path Initiative** is an important opportunity to advance the scientific basis for CDRH operations
- **NVCA is committed to collaborating with FDA** to identify new scientific and regulatory opportunities to get safe and effective medical devices and radiological products to market more quickly

Thank You



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