

# Stimulating Innovation in Medical Technologies

Carol Kelly

Executive Vice President

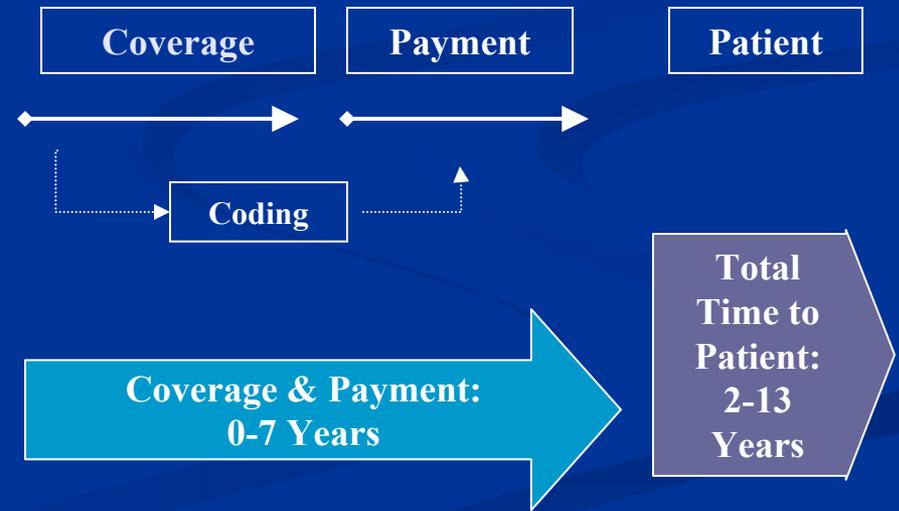
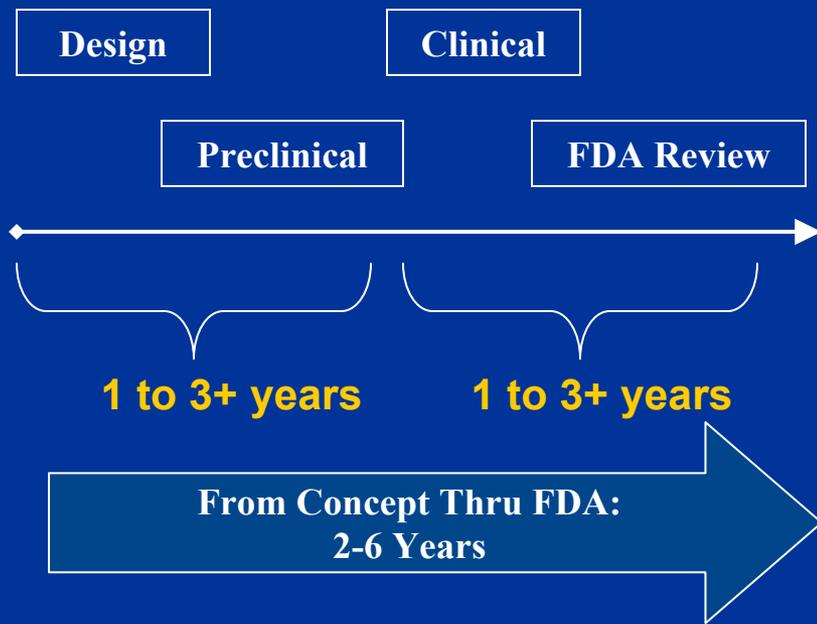
Advanced Medical Technology Association

November 8, 2004



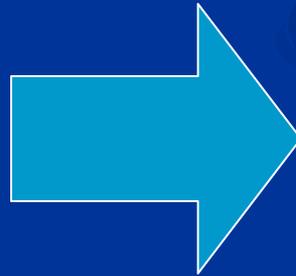
# FDA

# CMS



# AdvaMed Recommendations

- Clarity
- Consistency
- Appropriate evidence
- Reasonable payment



Successful  
Innovation  
for Patients



U.S. Department of Health and Human Services

# NIH News

National Institutes of Health

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## NIH Announces Strategy to Accelerate Medical Research Progress

**Washington, D.C.** — In a move to transform the nation's medical research capabilities, the movement of research discoveries from the bench to the bedside, National Institutes of Health (NIH) Director Elias A. Zerhouni, M.D., today laid out a series of far-reaching initiatives collectively as the NIH Roadmap for Medical Research.

Soon after becoming NIH Director in May 2002, Dr. Zerhouni convened a series of meetings to chart a "roadmap" for medical research in the 21<sup>st</sup> century — a process that identifies opportunities and gaps in biomedical research that no single institute at NIH could address but that the agency still needed to address.

"NIH must lead the way in instituting the changes in medical research necessary to improve the health of all Americans," HHS Secretary Tommy G. Thompson said. "It is clear that this is a compelling vision for the future of medical research and what will have the most profound impact on research and most importantly the health of all Americans."

"There has been a scientific revolution in the last few years. The opportunities for discovery have never been greater, but the complexity of biology remains a daunting challenge. A new strategy for medical research, NIH is uniquely positioned to spark the change needed to transform scientific knowledge into tangible benefits for people," said Dr. Zerhouni.

"We have made remarkable progress in medical research in recent decades, and NIH has changed the landscape of many diseases. However, very real — and very urgent — challenges remain," Dr. Zerhouni said. "NIH is now drawing all fields of science together in a concerted effort to meet these challenges head-on."

Developed with input from more than 300 nationally recognized leaders in academic medicine

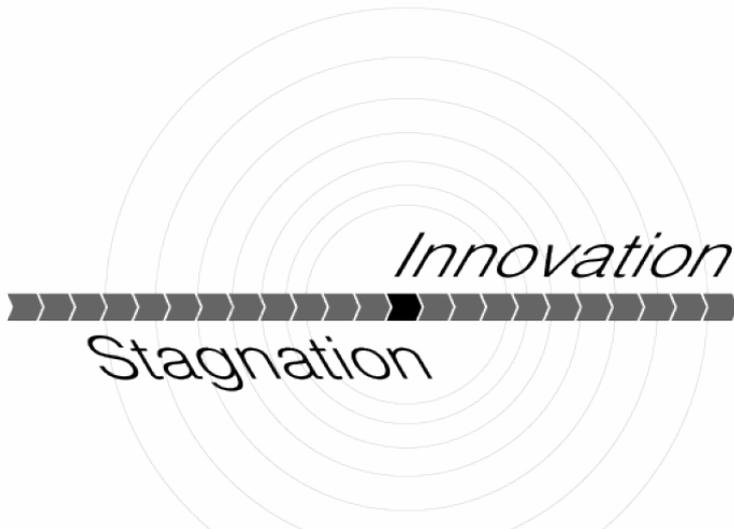


U.S. Food and Drug Administration



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This report replaces the version posted on March 16, 2004. It contains a revised Figure 2, which now reflects fiscal year data for both BLAs and NMEs, and minor editorial changes.



## Challenge and Opportunity on the Critical Path to New Medical Products



U.S. Department of Health and Human Services  
Food and Drug Administration

# Medicare

*...Appropriate evidence, reasonable payment...*

## ■ Coverage

- New vision
- Appropriate evidence
- Local coverage
- Guidances

## ■ Payment

- Outpatient PPS
- Inpatient add-on payment
- Coding changes
- Competitive bidding

# McClellan Vision

FDA clearance



Prompt coverage



Use in real-world settings



Ongoing data collection

(Electronic Health Records)



Feedback using information technologies



# Medicare Coverage Concerns

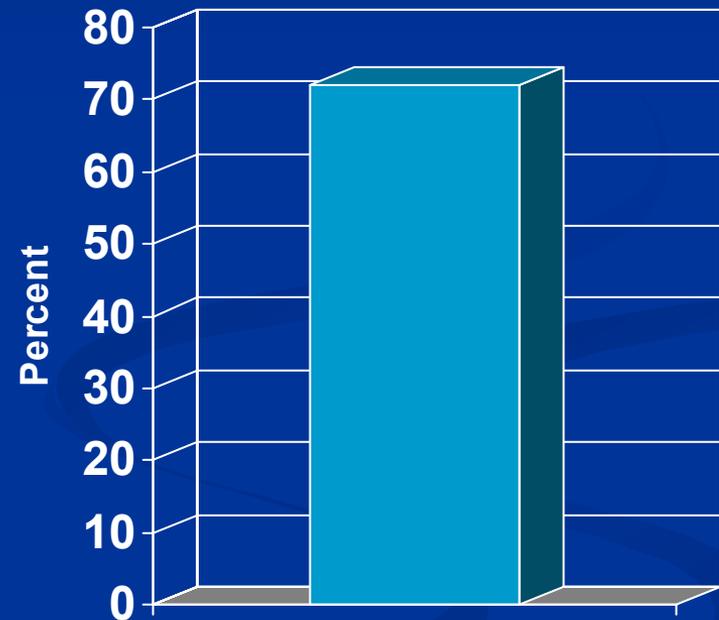
- Appropriate evidence
- Local coverage
- Guidances
- Changes in “indication-by-indication” approach
- Communication
- Consistency

# Medicare Payment Concerns

- Outpatient PPS
- New tech add-ons for inpatient PPS
- National temporary codes
- Competitive bidding
- DME prescription requirements
- Clinical lab fee schedule

# Medicare Matters...

- Most significant factors affecting product development?
- “Medicare reimbursement and coverage”



Source: “The State of the Medical Technology Industry,” Lewin Group for AdvaMed, 6/18/03

# FDA

*...Innovative strategies, better communication...*

- Data development
  - Model testing
  - Independent trials for new uses
  - Data summary template
  - Feedback
- Communication
  - Guidance documents
  - Reviewer education
- IVDs
  - Consistency in regulation
  - Guidelines on banked samples
  - Risk based approaches

# Data Development

- Model testing
- Independent trials for new uses
- Data summary template
- Feedback

# Communication

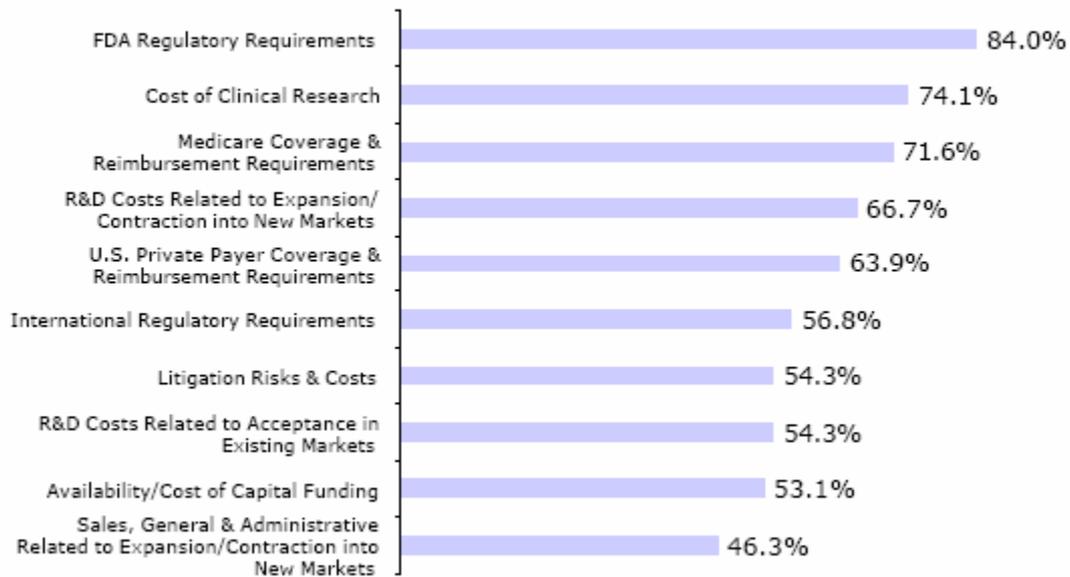
- Guidances
- Reviewer education

# IVDs

- Consistency in regulation
- Banked samples
- Risk-based approaches

**Chart 3.7**

**Top Ten Factors Affecting Companies' Ability to  
Develop New Medical Technologies Over Past Five Years, 2003**



*Source: AdvaMed Survey of Member Companies, 2003*