Changing National Landscape of Funding & Impact on Physician Scientists

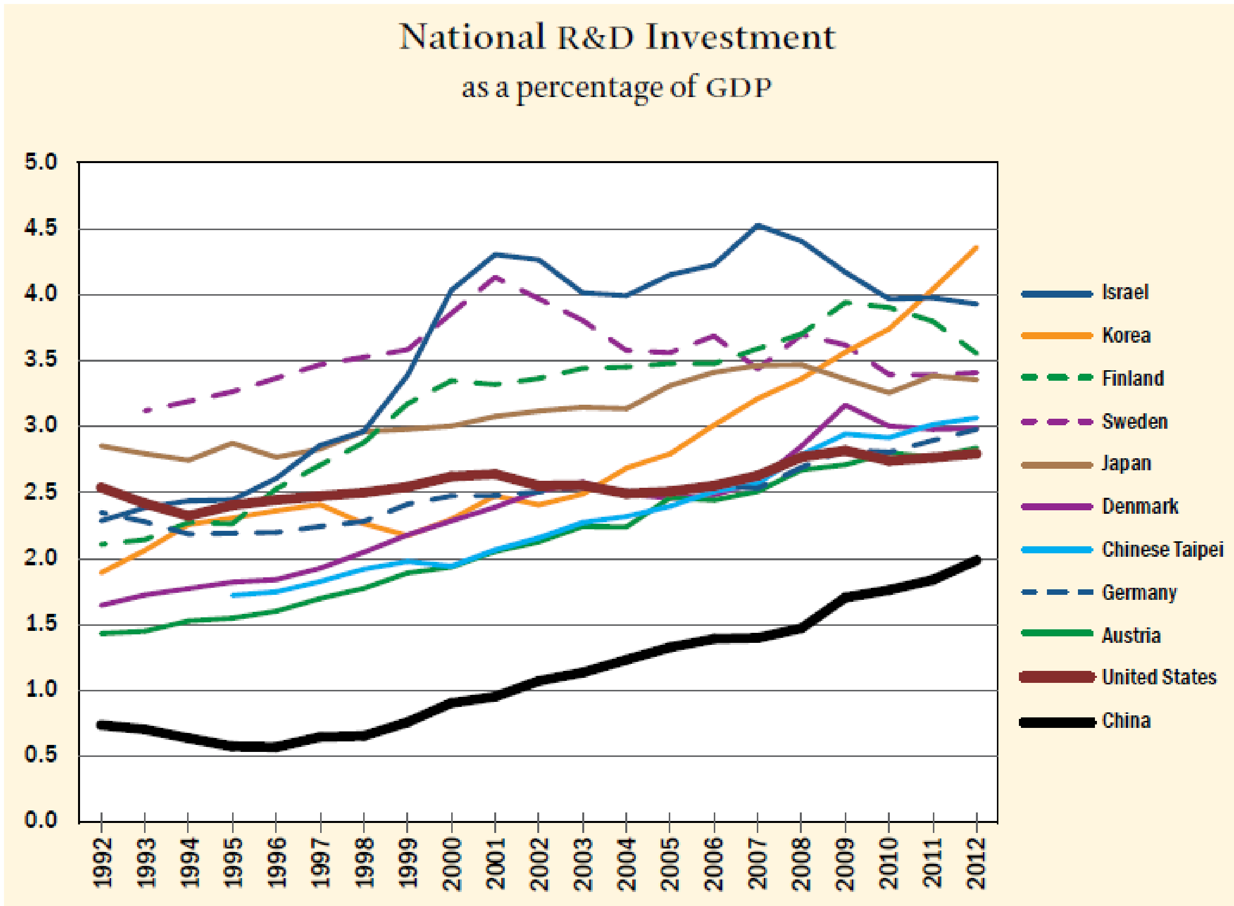
Victor J. Dzau
President, National Academy of Medicine

November 12, 2015
AAIM Third Consensus Conference on Physician Investigator Workforce

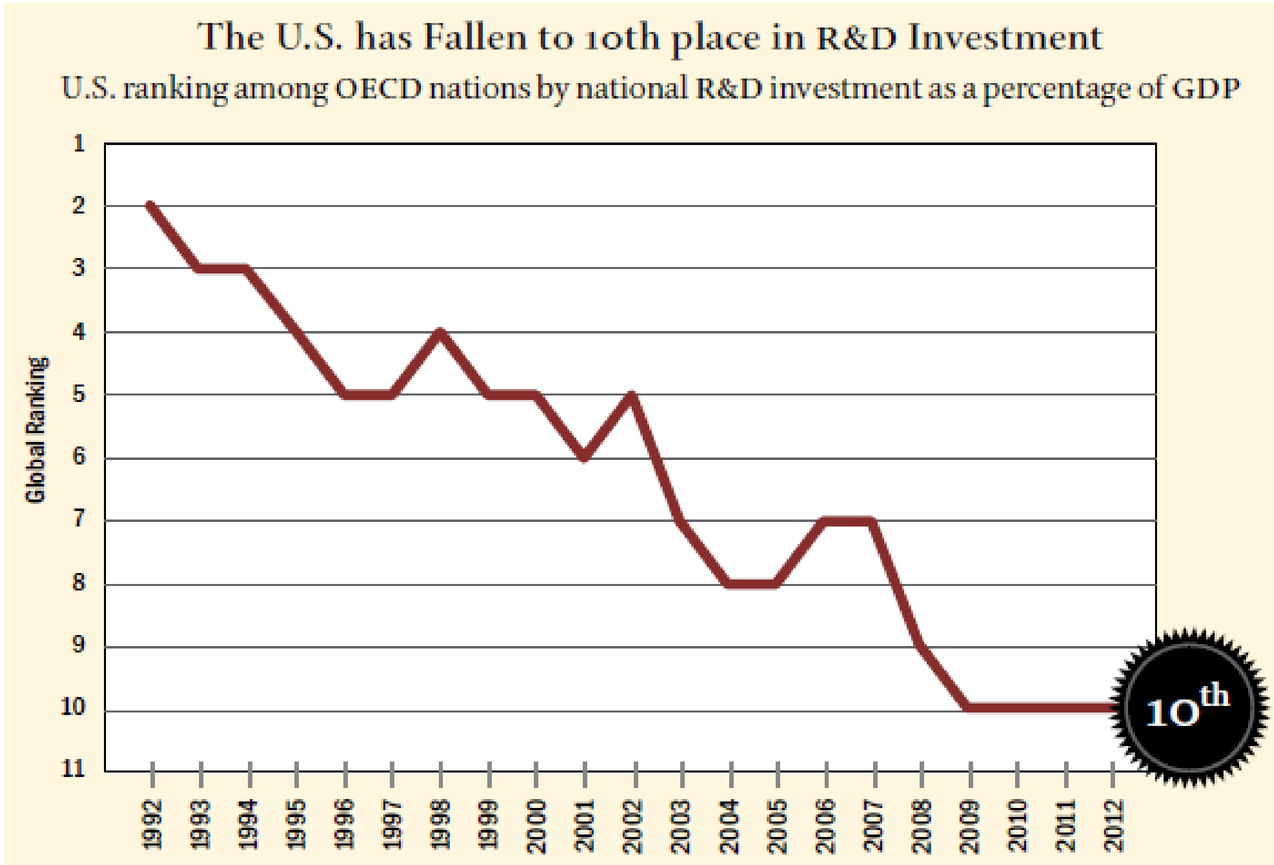
NATIONAL ACADEMY OF MEDICINE
Leadership • Innovation • Impact | *for a healthier future*

The US is at risk of losing its global scientific leadership

- US Share of total global investment declined by approximately 13% from 2004 to 2012 while the share of Asian economies increased by 7%
- NIH's purchasing power has been cut by about 25-30% compared to over a decade ago
- US Global share of research patents designated as most valuable declined from 73% in 1981 to 59% in 2011



Organisation for Economic Co-operation and Development, 2014



Organisation for Economic Co-operation and Development, 2014

EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

SCIENTIFIC DISCOVERY AND THE FUTURE OF MEDICINE

Restore the US Lead in Biomedical Research

Victor J. Dzau, MD; Harvey V. Fineberg, MD, PhD

Editorial page 145

Related article page 174

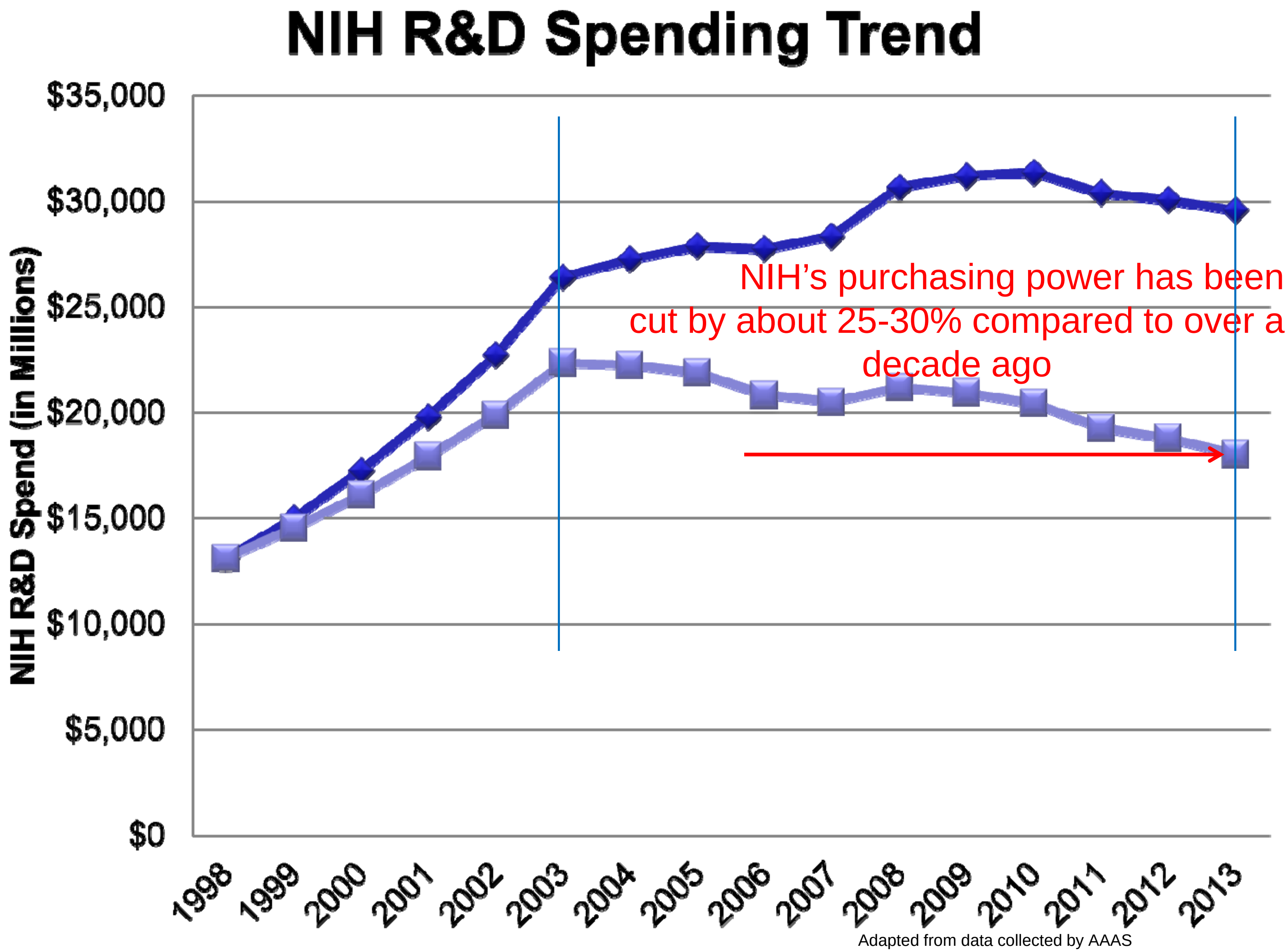
The US position as a global leader in biomedical research is being undermined. As compiled and presented in this issue of *JAMA* by Moses et al, one indicator after another demonstrates numerous other countries outpacing the United States in their commitment to research. US medical research spending increased 6% per year from 1994 to 2004 but only 0.8% per year between 2004 and 2012. The United States' share of total global investment declined by approximately 13% from 2004 to 2012 while the share of Asian economies increased by 7%. Patent output reflects these declines—the United States' global share of research patents designated as most valuable declined from 73% in 1981 to 59% in 2011.[1]

ics such as clean skies, fuel cells, and innovative medicines. These JTIs set their own research agendas and independently award funding. The United States has much work to do to improve partnerships among governments, academia, industry, and private philanthropy.[3]

It is the responsibility of the research community to ensure that money for research will be used effectively and efficiently. A first step is to reduce redundancy and duplication of research through better grant selection and coordination. There is also a need to reduce administrative costs related to research. A National Research Council report noted that one southeastern medical school experienced a 300% cumulative growth rate in compliance and quality assurance costs between 2001 and 2010, while sponsored expenditures increased by only 125% during the same period.[4] More dollars are spent in meeting research regulations while direct pro-

US needs strategy & commitment to research funding

- New sources of funding
  - E.g., repatriation of foreign capital, innovation bonds, research trusts, tax checkoffs
- Ensure funding is used effectively and efficiently
  - Avoid duplication
  - Reduce compliance costs
- Roadmap that sets research priorities
- The US should develop a long term strategy for research investment that ensures multi-year stability
  - Tied to index and performance


NIH R&D Spending Trend
$35,000
$30,000
$25,000
$20,000
$15,000
$10,000
$5,000
$0
NIH R&D Spend (in Millions)
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
NIH's purchasing power has been cut by about 25-30% compared to over a decade ago
Adapted from data collected by AAAS

Traditional perspective of innovation in medicine

- Driven by research
- Funded primarily by NIH, other federal sources and industry
- Conducted mainly in academic medical centers
- By researchers often away from practice
- Training is strictly science based

Challenges confronting AHCs

- Complex organizations
- Balance between academic and clinical missions
- Research & clinical funding
- NIH budget
- Academic subsidy
- US health care reform impact
- Future of physician scientists

PERSPECTIVE

Balancing AMCs' Missions and Health Care Costs — Mission Impossible?

Elizabeth G. Nabel, M.D., Timothy G. Ferris, M.D., M.P.H., and Peter L. Slavin, M.D.

Importance of the physician scientist

- Vital in transforming clinical observations into testable research hypotheses and translating research findings into medical advances
  - “bedside-to-bench” and the “bench to bedside” approach
- Valuable teachers to medical students
- Over the last 25 years, 37 percent of Nobel Laureates in Physiology or Medicine had an MD
- Over the Lasker Awards’ last 30 years, 41 percent of the Basic Awards and 65 percent of the Clinical Awards have gone to MDs
- 70 percent of the chief scientific officers at the top 10 pharmaceutical companies have an MD

Challenges Facing Physician Scientists

- Personal
  - Debt-burden
  - Work-life balance
  - Compensation
- Training
  - Physician-scientists have less time to acquire research skills and demonstrate potential compared to pure PhDs due to time for clinical training
- Environmental
  - Decline in research funding
  - Competing against greater numbers of PhDs for a smaller funding pool
  - Challenge in getting a research career started
  - Increasingly time-consuming and demanding requirements to maintain clinical credentials
- Institutional
  - Insufficient institutional support for research
  - Tension between clinical and research missions
    - Financial opportunities in practice offer an attractive option for clinically-trained physician-scientists
    - Over-reliance on relative value units discourages academic pursuits
  - Difficulty finding mentors
- Societal
  - Lack of inspiration and exposure to scientific career options
  - Inadequate appreciation of science and research processes
  - Relative societal value of different professions

Recent trends

- The physician scientist workforce has experienced a small but statistically significant decline over the past 10 years
- The average age of the physician scientist is increasing
- The award rate of NIH Research Project Grants and R01 awards is decreasing

Initiatives addressing the physician scientist pipeline

- IOM report
  - 1994 Careers in Clinical Research: Obstacles and Opportunities
- NIH
  - 1995: NIH Director's Panel on Clinical Research
  - 2014: NIH Physician-Scientist Workforce Working Group Report
- AAMC
  - task force on clinical research by physician-scientists
- APM/AAIM
  - 2007 – present: Physician Scientist Initiative
- Howard Hughes Medical Institute
- NIH Lasker Clinical Research Scholar Program
- Foundations
  - Burroughs Wellcome Fund
  - Doris Duke Charitable Foundation
  - Robert Wood Johnson Foundation
  - Lasker Foundation

NIH Physician-Scientist Workforce Report: Recommendations

1. NIH should sustain strong support for the training of **MD/PhDs**.
2. NIH should shift the balance in National Research Service Award (NRSA) postdoctoral training for physicians so that a greater proportion are supported through **individual fellowships**, rather than institutional training grants.
3. NIH should continue to **address the gap in RPG** award rates between new and established investigators.
4. NIH should adopt rigorous and effective **tools for assessing** the strength of the biomedical workforce, including physician-scientists, and tracking their career development and progression.
5. NIH should establish a **new physician-scientist-specific granting mechanism** to facilitate the transition from training to independence.
6. NIH should **expand Loan Repayment Programs** and the amount of loans forgiven should be increased to more realistically reflect the debt burden of current trainees.
7. NIH should support **pilot grant programs** to rigorously test existing and novel approaches to **improve and/or shorten research training for physician-scientists**.
8. NIH should intensify its efforts to **increase diversity** in the physician-scientist workforce.
9. NIH should **leverage the existing resources of the Clinical and Translational Science Awards (CTSA)** program to obtain maximum benefit for training and career development of early-career physician-scientists.

What seems to be effective to date

- MD/PhD
- Physician scientist training program
- Career development awards

What seems to be effective to date

- MD/PhD
  - In 2012, MD/PhDs overall had higher award rates for RPGs (24.6 percent) than MDs (21.7percent) or PhDs
  - Almost 80 percent of a cohort of MD/PhDs with past MSTP Appointments (1980-1989) have applied for RPGs, and approximately 78% have been successful
- Physician scientist training programs
  - ABIM research pathway career outcomes
    - 91% still involved in research
    - Average 58.6% of total professional effort spent in research
- Career development awards
  - RPG award rates for first-time RPG applicants with a prior LRP or K award are much higher than for those without: For MDs: 44.1 percent vs 9.2 percent and for MD/PhDs: 60.0 percent vs 10.1 percent

Future Needs

- Increase and stabilize research funding
- Align the number of scientific training positions and careers
- Aligning and incentivizing careers with how science is being carried out
  - Team science
- Broaden career paths for physician scientists
- Creating an a culture that fosters scientific discovery
- Rethink and expand the definition of physician scientist consistent with trends in health & medicine

"I skate to where the puck is going, not where it has been."

-Wayne Gretzky

The role of academic health science systems in the transformation of medicine

Victor J Dzau, D Clay Ackerly, Pamela Sutton-Wallace, Michael H Merson, R Sanders Williams, K Ranga Krishnan, Robert C Taber, Robert M Califf

The challenges facing the health of communities around the world are unprecedented, and the data are all too familiar. For 5 billion people living in developing countries, environmental factors and inadequacies in hygiene, economic development, and health-care access are the main causes of shortened life expectancies. Improvements in health status, including reductions in infant mortality and declining incidence of infectious diseases, are being met by the new epidemics of obesity, diabetes mellitus, and cardiovascular disease.[1]

Developed countries are beset by disparities in access

In order to achieve transformation, two distinct translational blocks or gaps in the discovery-care continuum must be overcome.[11,12] The first is the gap between a scientific discovery and its clinical translation (ie, from bench to bedside); the second is the gap between expert acceptance of the application and its broad adoption in practice by local and global communities (ie, from bedside to population). AHSCs traditionally give their discoveries to industry at the first gap and to practising physicians at the second gap, thereby creating barriers and inefficiencies. We believe that AHSCs are

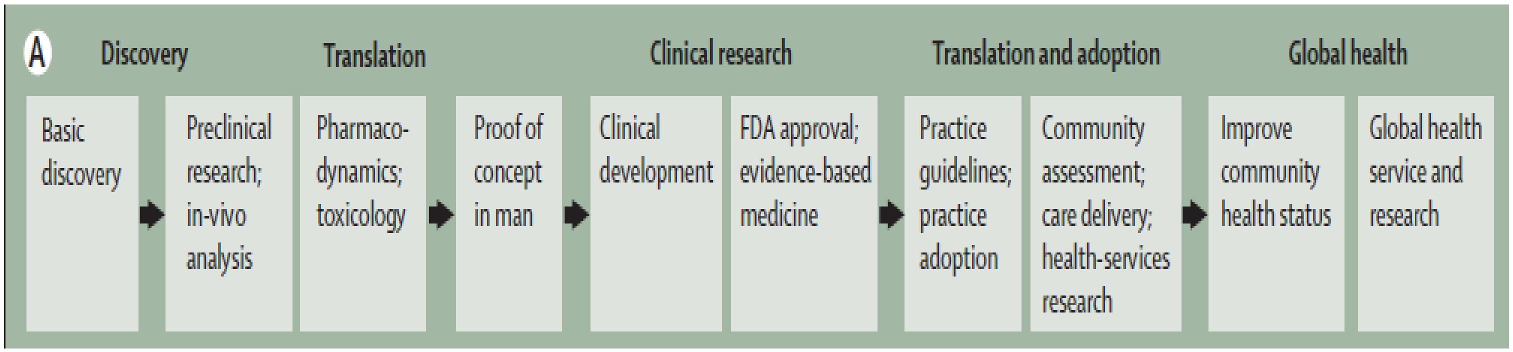
Lancet 2010; 375: 949-53

Published Online
October 1, 2009
DOI:10.1016/S0140-6736(09)61082-5

See Online/Comment
DOI:10.1016/S0140-6736(09)61594-4

Duke Medicine, Durham, NC, USA (Prof V J Dzau MD, D C Ackerly MD, P Sutton-Wallace MPH,

Discovery to Care Continuum



T1
Bench science
Animal models
Epidemiology

T2
First-in-human studies
Clinical trials expertise
Statistics
Ethical conduct of research
Regulatory

T3
Implementation Science
Evidence-based reviews

T4
Community and Global Health

Source: Dzau et al, Lancet 2009

Aligning Duke Medicine: Discovery to Care Continuum

Duke Medicine

Discovery Science → Experimental Medicine → Clinical Trials → Implementation Science → Global and Population Health

Discovery Science	Experimental Medicine	Clinical Trials	Implementation Science	Global and Population Health
Discovery Laboratories	Duke Clinical Research Unit	Duke Clinical Research Institute	Duke Center for Community Research	Duke Global Health Institute

Duke Translational Medicine Institute

Duke Institute for Health Innovation

Transforming Academic Health Centers for an Uncertain Future

Victor J. Dzau, M.D., Alex Cho, M.D., M.B.A., William ElLaissi, M.B.A., M.H.A., Ziggy Yoediono, M.D., M.B.A., Devdutta Sangvai, M.D., M.B.A., Bimal Shah, M.D., M.B.A., David Zaas, M.D., M.B.A., and Krishna Udayakumar, M.D., M.B.A.

Academic health centers (AHCs) have long led the advancement of science and medicine by pursuing missions of clinical care, research, and education. AHCs have been places where important fundamental and translational research is performed and medical innovations are created and tested. Given the dramatic changes ahead in health care and deteriorating research funding, can this record of achievement continue, or do AHCs in the United States face a growing risk of extinction?[1]

AHCs should aspire to lead the transformation of healthcare

Reorganizing biomedical research and health delivery systems into a **seamless continuum** from discovery to clinical delivery to community health. **Moving from Academic Health Center (AHC) to Academic Health Sciences System (AHSS).**

"Bench to Bedside to Population"

- *Integration of care delivery with population health*
- *Seamless translational model of discovery-care continuum*
- *Effective use of information for care & research : Learning Health System*
- *Emphasize & accelerate Innovation*
- *Community & Global Health*
- *Globalization*

Dzau VJ et al Lancet 2010

Dzau VJ et al NEJM 2013

Learning Healthcare Systems

Healthcare research & innovations are slow to disseminate into clinical practice. Research is generally seen as a separate activity instead of being integrated with clinical practice.

A learning health care system is one in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the care process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the care experience. –IOM (2012)

- AHC as a living laboratory
- Use of integrated clinical & research data to develop care redesign and novel care model
- Use of large datasets and informatics to improve health
- Use innovation to transform health
- Developing the innovation culture, ecosystem & infrastructure

Source: IOM Roundtable on Value & Science-Driven Health Care, 2012.

Research Funding Sources

- NIH
- Industry
- Foundations and non-profits
- Philanthropy
- Other sources
  - PCORI
  - CMMI
  - AHRQ

Opportunities for physician scientists

- Data & quantitative sciences
- Public & population Health
- Precision medicine
- Behavioral & social sciences
- Regulatory & implementation sciences

Summary: Influence of NIH, ACA & changing environment

- Strained traditional research funding
- Enhanced research in clinical care and health care delivery
- Expanded the definition of innovation
- Imperative to maintain the proper balance between curiosity-driven, basic research and applied research

Innovation opportunities

- Precision Medicine
- Regenerative Medicine
- Bio & tissue engineering
- Synthetic Biology
- 3D Printing
- Sensing technologies
- Big data and analytics

Some final provocative thoughts

- Do we understand and are we connecting with the next generation? Or are we just talking to ourselves?
- Concentrate on what works
- It is a matter of resources & scale
- Bold curricular & pathway reform
- Need to be adaptive & resilient
- Clearly define our goal

Provocative thoughts

Are we listening to the young people? Or are we just talking to ourselves?

- If money is a key driver, how come there are so many students service-oriented programs, such as Teach for America, Peace Corps, AmeriCorps?
- Are we lacking inspirational goals and role models?
- Are we failing to connect with young people (Millennials , 21st century)?
- Is it a societal issue?

Provocative thoughts

Concentrate on what works

- MD/PhD pathway seems to work. Focus?
- Physician scientist pathway seems to work. Develop more?

It is a matter of resources & scale

- How many do we need? Currently at 14000, how many will we need in the future?
- If we know how many, and the number is small, pay their full tuition
- If larger, then only bet on those who are likely to succeed and pay off their debt.
- What is the correct balance of basic, translational, clinical, and health researchers? Should they be supported differently?

Bold curricular & pathway reform

- Data suggests that interest starts in high school or earlier. Recruit and focus on them. Create an early pathway for PS.

Provocative thoughts

Be Adaptive & Resilient

- We need to live in the real world and not keep looking back. Need to adapt and be resilient.
- Understand healthcare trends and innovation.
- Redefine academic medicine, science and innovation.
- Rethink and broaden definition of physician scientist.

Be clear on our goal

- What is the endpoint of PS? How do we measure success? Nobel Prize? Research grants & publications? Health outcomes?

“I skate to where the puck is going, not where it has been.”

-Wayne Gretzky

Thank Celynne Balatbat & Leigh Carroll

&

Good Luck

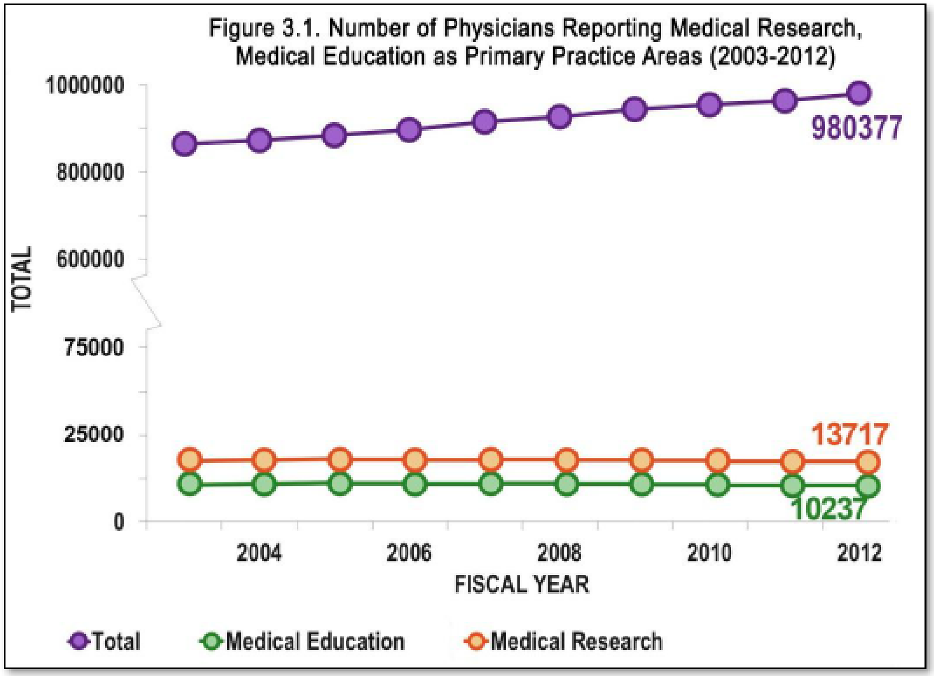
Some provocative thoughts

- Why are we attracting less physician scientists? How can we motivate and inspire the next generation of physician scientists?
- How do we develop a bolder approach to developing physician scientists?
- What is the value of physician scientists? How should we measure success for physician scientists/physician scientist training programs?
- What is the optimal number of physician scientists? How does this affect the way we allocate resources?
- Should we rethink the definition and pathway of physician scientists in light of recent trends in health and medicine?
- Are we just talking to ourselves? Who else should we include in this conversation?

Importance of the Physician Investigator

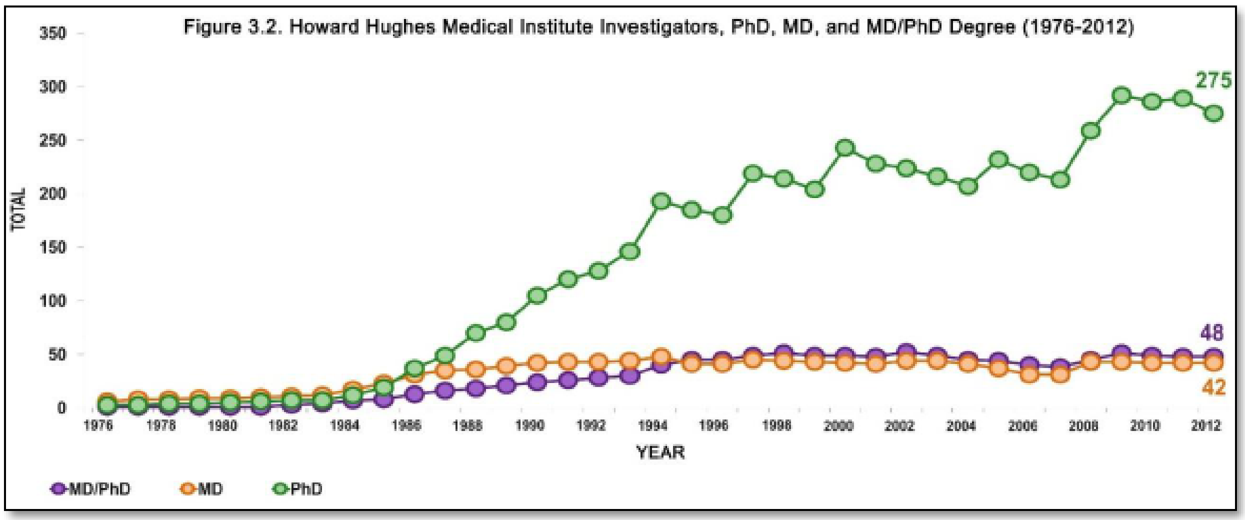
The Nobel Prize in Chemistry 2012

Decline of the Physician Investigator

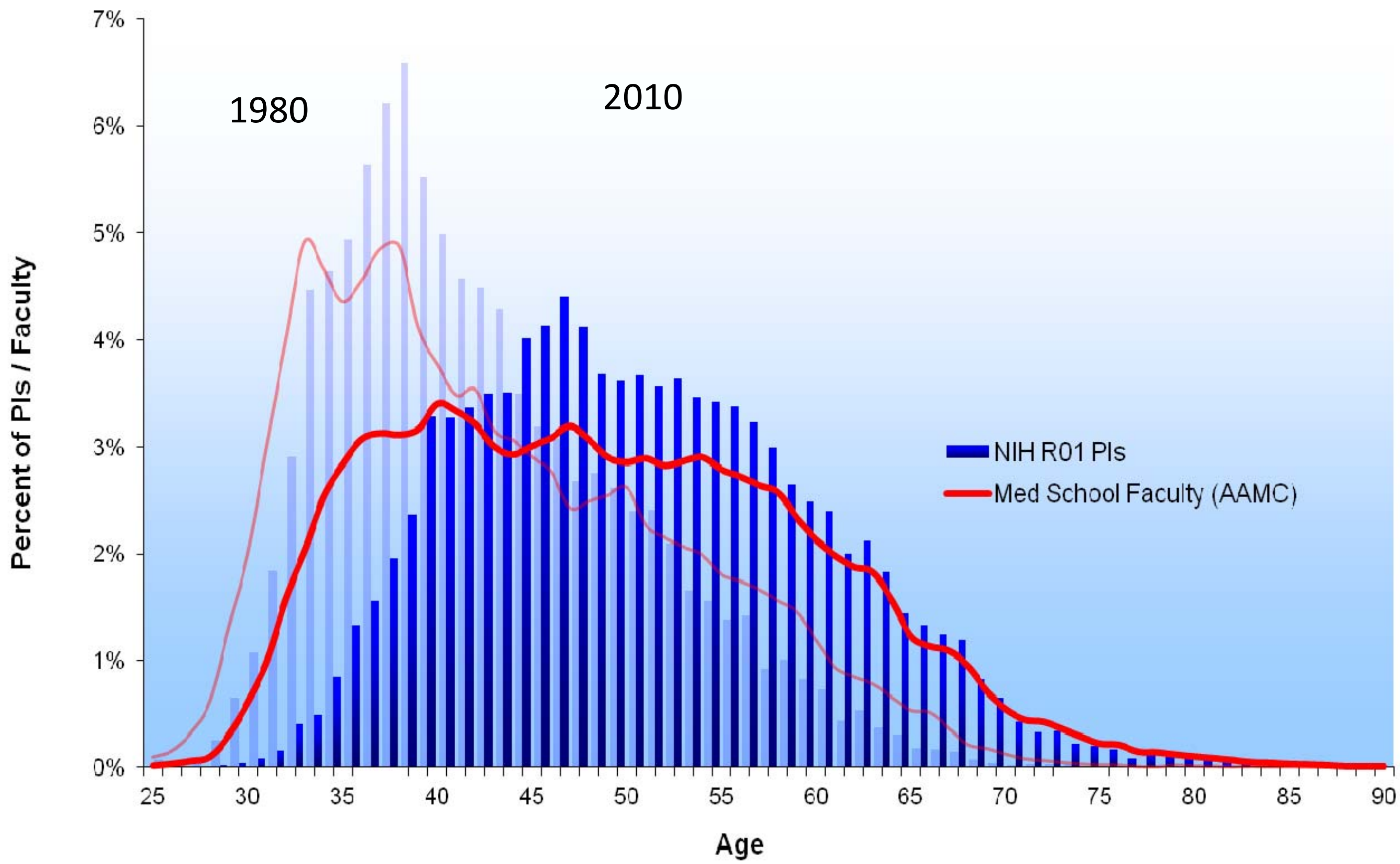


SOURCE: Those MD-holding Physicians that indicated they were in primarily Medical Education or Medical Research from the American Medical Association (AMA) Physician Masterfile Annual Year-end Snapshots.

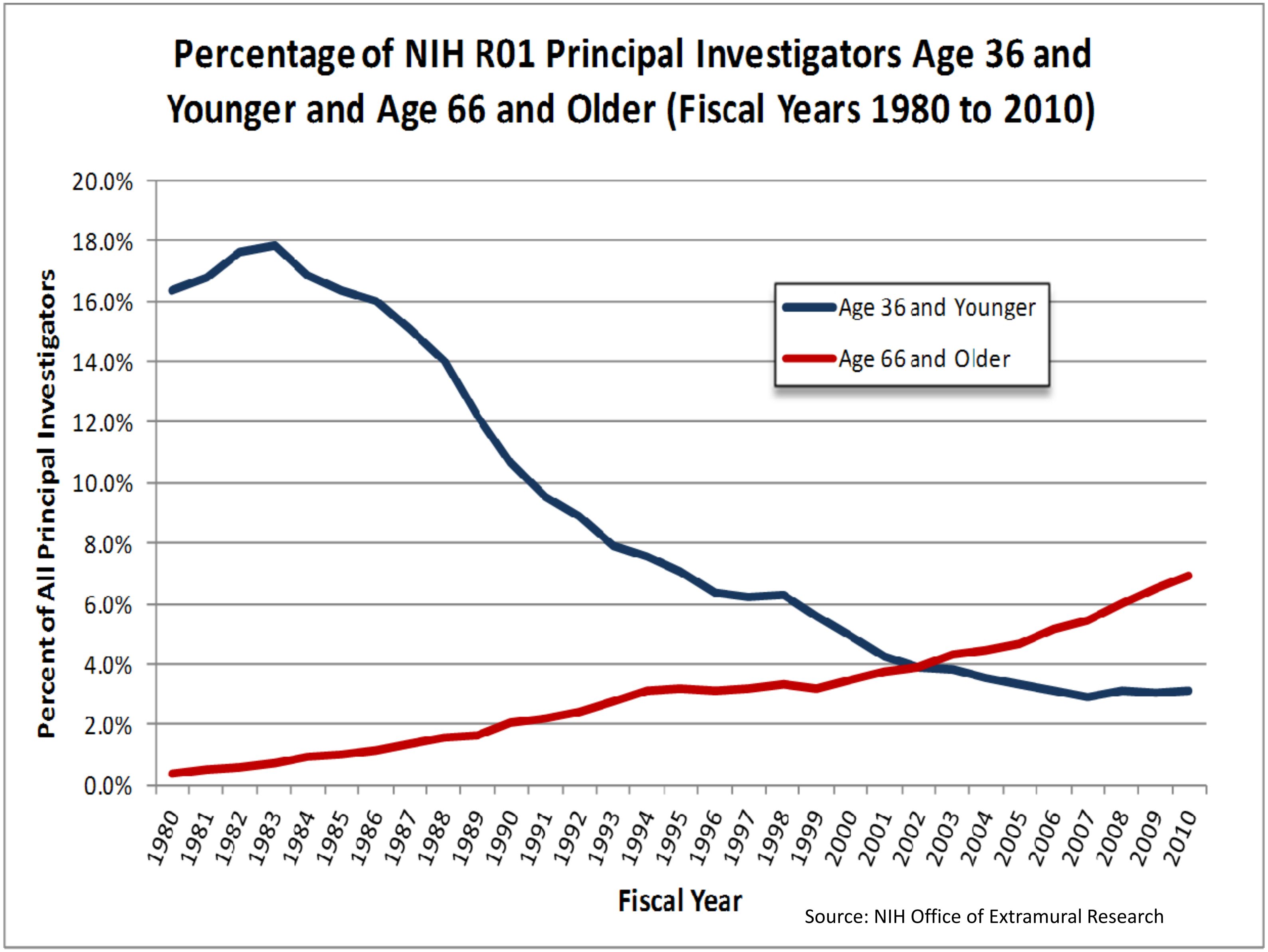
Decline of the Physician Investigator



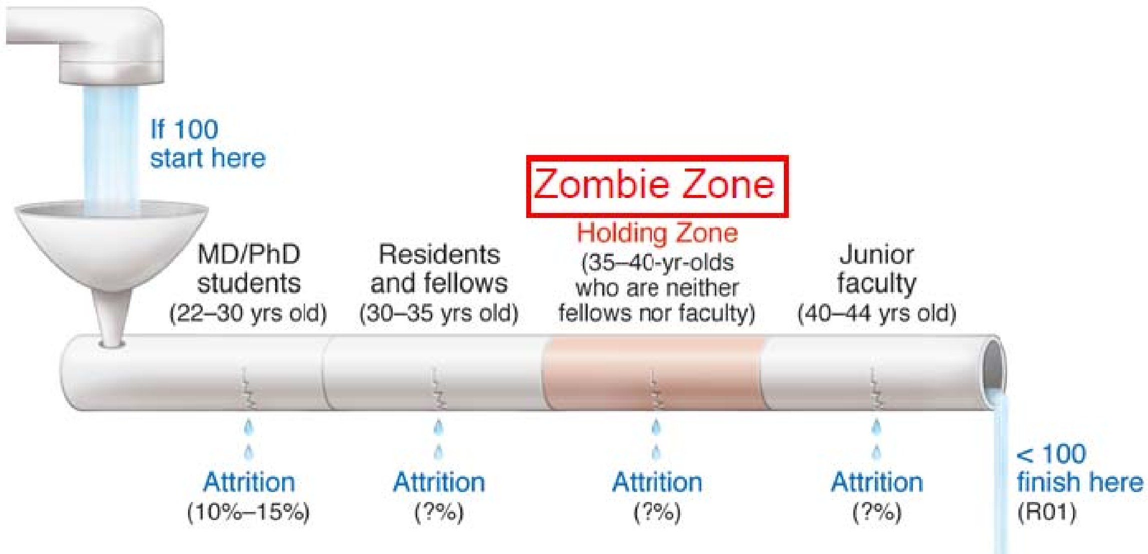
Changing demographics of physician scientists (1980 vs 2010)

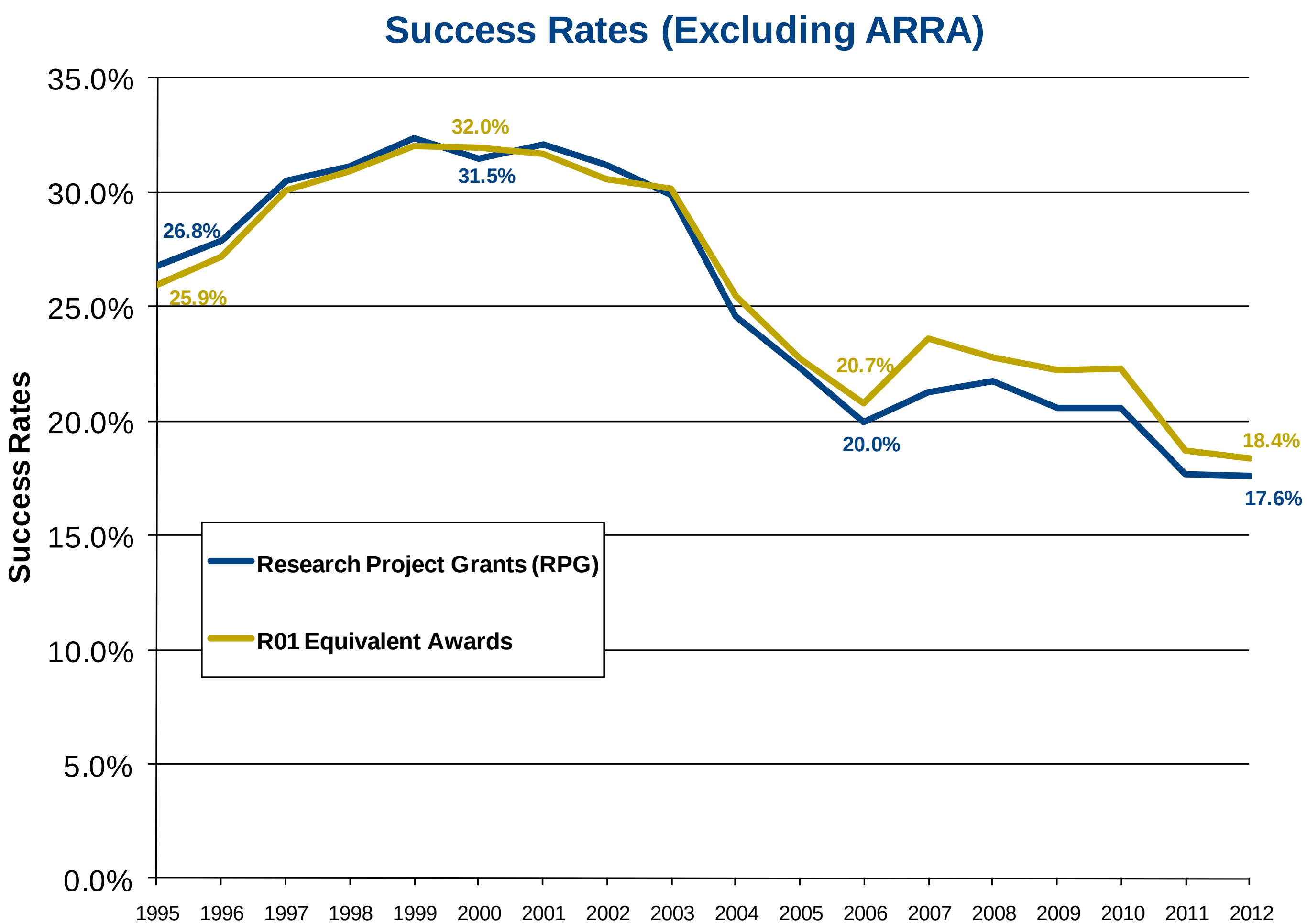


Source: AAMC



Percentage of NIH R01 Principal Investigators Age 36 and Younger and Age 66 and Older (Fiscal Years 1980 to 2010)
20.0%
18.0%
16.0%
14.0%
12.0%
10.0%
8.0%
6.0%
4.0%
2.0%
0.0%
Percent of All Principal Investigators
Age 36 and Younger
Age 66 and Older
1980
1981
1982
1983
1984
1985
1986
1987
1988
1989
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
Fiscal Year
Source: NIH Office of Extramural Research


If 100
start here
Zombie Zone
Holding Zone
(35–40-yr-olds
who are neither
fellows nor faculty)
MD/PhD
students
(22–30 yrs old)
Residents
and fellows
(30–35 yrs old)
Junior
faculty
(40–44 yrs old)
Attrition
(10%–15%)
Attrition
(?%)
Attrition
(?%)
Attrition
(?%)
< 100
finish here
(R01)



FASEB
Federation of American Societies for Experimental Biology

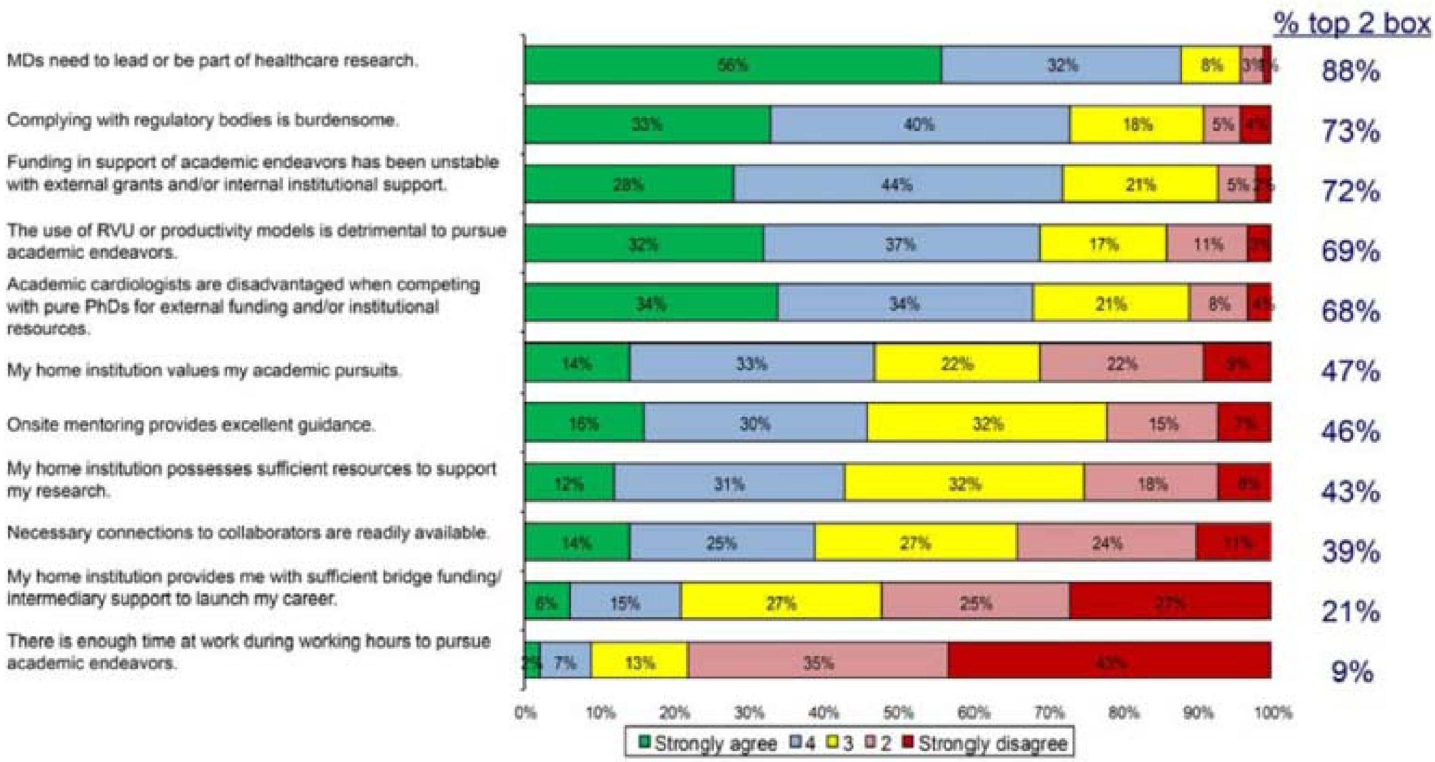


Figure 3. Perceived Obstacles to Academic Pursuits
Survey identified complying with regulatory burden, unstable funding, detrimental use of RVUs, being disadvantaged when competing with PhDs, lack of good onsite mentoring, home institution lacking resources, lacking collaborators, lacking bridge funding, and insufficient time during work hours as major obstacles.

Top Reasons from NIH Official for K-Grant Failure

Applicant appears to be inadequately prepared nor committed to research. The applicant did not demonstrate sufficient skill in the area of proposed research as seen by lack of prior first author publication and lack of valid preliminary data in the proposal. The applicant did not demonstrate commitment to research by lack of prior dedicated research time. Furthermore, the applicant seems to suddenly jump into the proposed research without indication of prior experience, preparation, or believable motivation.

Career development plan appears to be poorly designed. Being career development grant, reviewers expect to see career development plan that integrates well with research plan. Often, applicants fail to demonstrate how the proposed research can directly contribute to their career development.

Research proposal is poorly developed. Being early career, applicants have the tendency to propose projects that cannot plausibly be completed. Furthermore, research plans lack focus; therefore, reviewers doubt that meaningful results can be accomplished for both advancement of science and career development.

Mentor does not appear to have the ability to help the mentee. Mentor not having NIH R01 level type of funding raises doubts about his/her ability to financially help the mentee if the research encounters difficulties or needing new methods. Mentor's letter may not match applicant's career development plans; consequently, reviewers interpret this mismatch as mentor being unwilling or unable to commit the necessary effort to help the mentee. Sometimes, the mentor does not demonstrate having expertise in the area of proposed research; thus, mentor will not be able to help. Since mentoring is an extraordinary crucial part of career development, perception of an inadequate mentor will doom the proposal even all other sections are excellent.

The “academic subsidy”

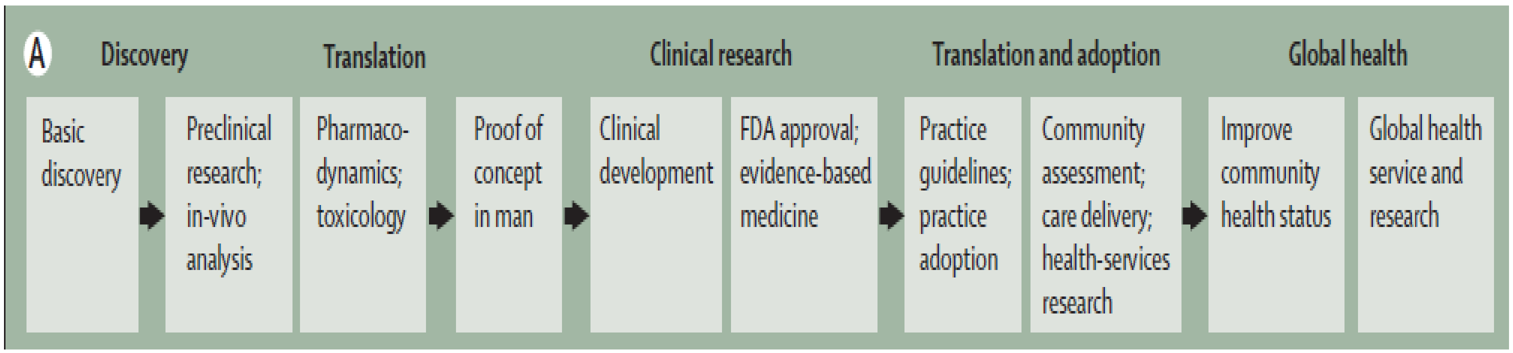
Currently:

- 30-40% “match” required for every $1 of NIH direct cost
- Many schools report medical education costs them $80-100K per student per year
- Depends on annual subsidy from clinical enterprise, endowments & philanthropy

In the future?

- With declining clinical reimbursement, weak economy and reduced NIH funding, academic funding gap will increase significantly

Discovery to Care Continuum



T1
Bench science
Animal models
Epidemiology

T2
First-in-human studies
Clinical trials expertise
Statistics
Ethical conduct of research
Regulatory

T3
Implementation Science
Evidence-based reviews

T4
Community and Global Health

Source: Dzau et al, Lancet 2009

Medical Scientist Training Program

- Currently has 45 participating programs with a total of 890 trainees

Defining the Mission

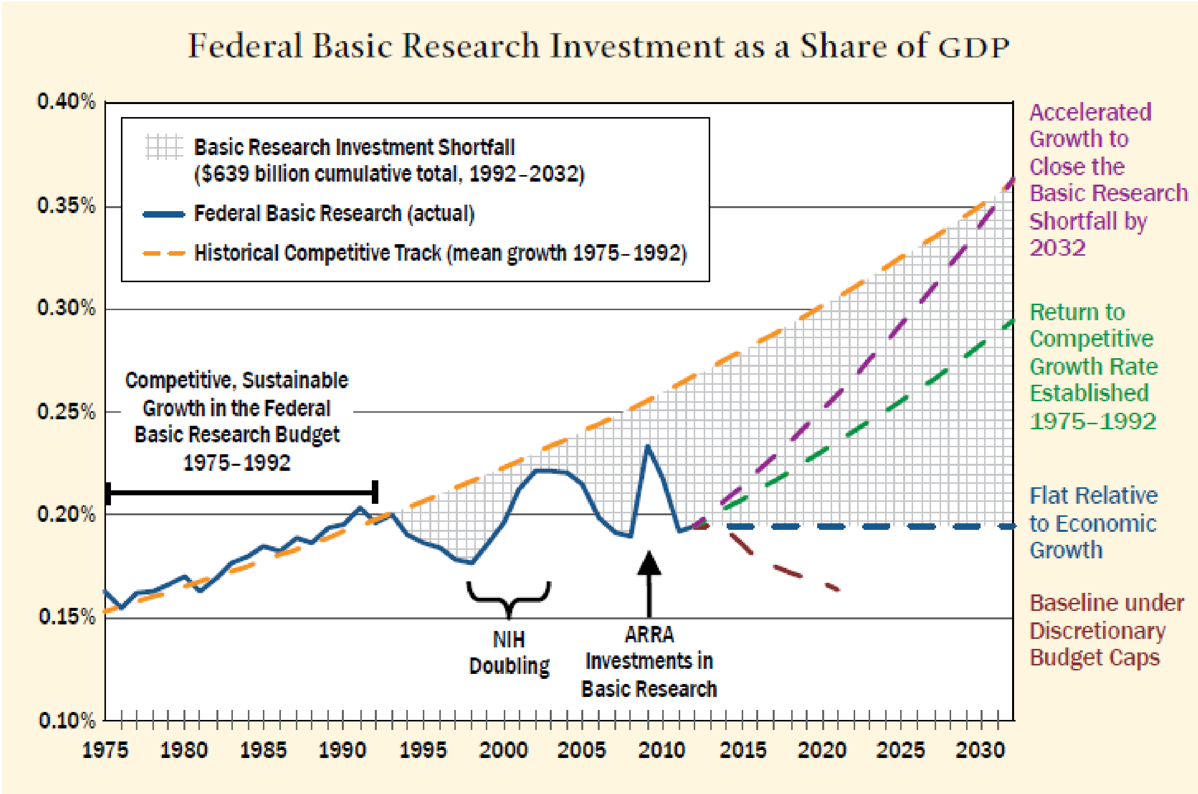
"As a world-class academic & healthcare system, Duke Medicine strives to transform medicine and health locally and globally through innovative scientific research, rapid translation of breakthrough discoveries, educating future scientific and clinical leaders, advocating and practicing evidence-based medicine to improve community health and leading efforts to eliminate health inequalities."

--Duke Medicine *Mission Statement 2006*

Summary of Trends in NIH Funding FY1995-FY2012

	FY1995	FY2012	% Change
NIH Budget (in millions)	$11,300	$30,860	173.1%
R01 Equivalent Funding ($ millions)	$4,718	$11,022	133.6%
Total # R01 Equivalent Grants	21,680	26,285	21.2%
R01 Equivalent Applications	22,542	29,627	31.4%
Ave. $ per R01 Equivalent (in thousands)	$217.6	$419.3	92.7%
# of R01 Equivalent Awards	5,849	5,437	-7.0%
R01 Equivalent Success Rates	25.9%	18.4%	-29.0%

FASEB
Federation of American Societies for Experimental Biology


Federal Basic Research Investment as a Share of GDP
Basic Research Investment Shortfall ($639 billion cumulative total, 1992–2032)
Federal Basic Research (actual)
Historical Competitive Track (mean growth 1975–1992)
Competitive, Sustainable Growth in the Federal Basic Research Budget 1975–1992
NIH Doubling
ARRA Investments in Basic Research
Accelerated Growth to Close the Basic Research Shortfall by 2032
Return to Competitive Growth Rate Established 1975–1992
Flat Relative to Economic Growth
Baseline under Discretionary Budget Caps
0.40%
0.35%
0.30%
0.25%
0.20%
0.15%
0.10%
1975
1980
1985
1990
1995
2000
2005
2010
2015
2020
2025
2030

Decline in Research Funding

- The United States' share of total global investment declined by approximately 13% from 2004 to 2012
- NIH's purchasing power has been cut by about 25-30% compared to over a decade ago
- The United States' global share of research patents designated as most valuable declined from 73% in 1981 to 59% in 2011.

MD/PhDs

- NIGMS-sponsored Medical Student Training Program (MSTP)
- NIH Graduate Partnership Training Program

Other Pathways

- ABIM
  - Program that combines training in research with training in clinical internal medicine and its subspecialties
- ??Physician Scientist Training Programs
  - Number of years in clinical specialty and subspecialty training are reduced to accommodate more training in clinical or laboratory-based research

NIH Lasker Clinical Research Scholars Program

- Provides substantial and protected full-time support for medical and dental scientists for up to 12 years

Career Development Awards

- Mentored Clinical Scientist Development Award (K08) – Provides mentored research and career development experiences for health professional doctorates in fields of biomedical and behavioral research.
- Mentored Patient-Oriented Research Career Development Award (K23) – Provides mentored research and career development experiences for health professional doctorates in patient-oriented research.
- Pathway to Independence Award (K99/R00) - facilitates a timely transition of outstanding postdoctoral researchers from mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions, and provides independent NIH research support during the transition that will help these individuals launch competitive, independent research careers
- Lasker