NIH: The View from 10,000 Feet

University of Illinois at Urbana-Champaign

Sally J. Rockey, PhD
Deputy Director for Extramural Research
National Institutes of Health

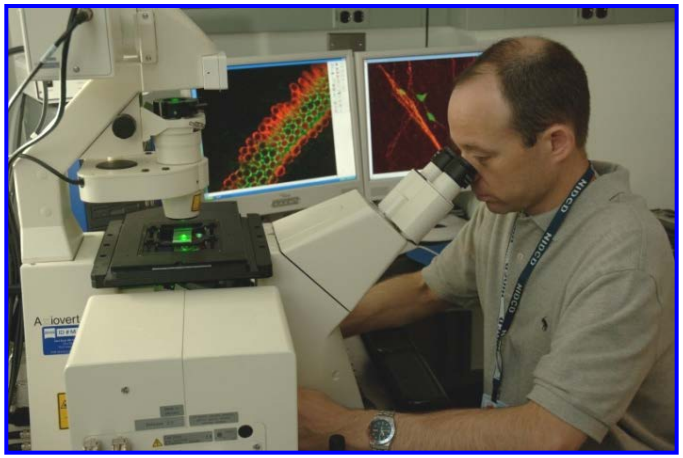
National Institutes of Health
Office of Extramural Research

WINNING *the* FUTURE

NIH: Steward of Biomedical & Behavioral Research for the Nation

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems…

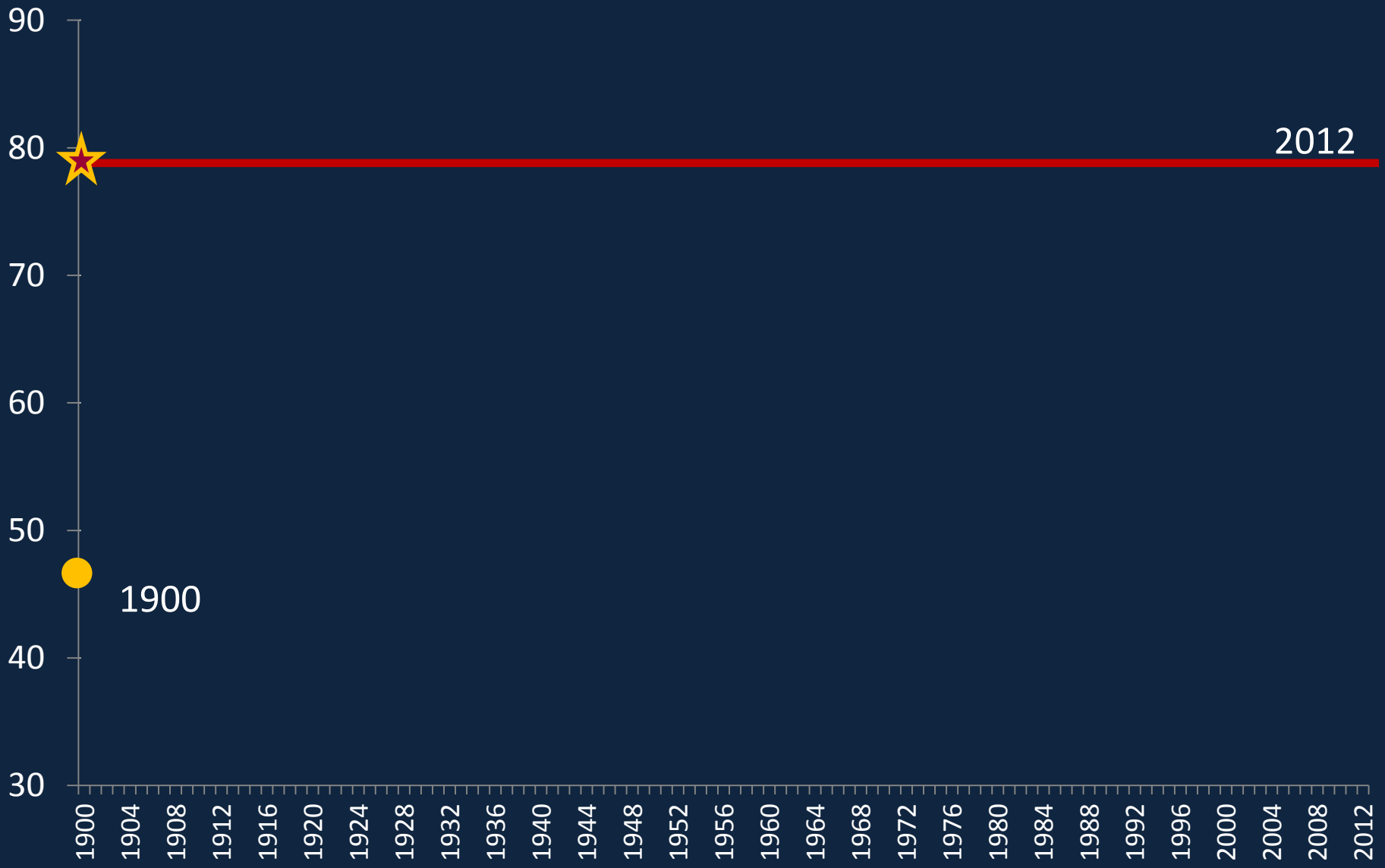
…and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.



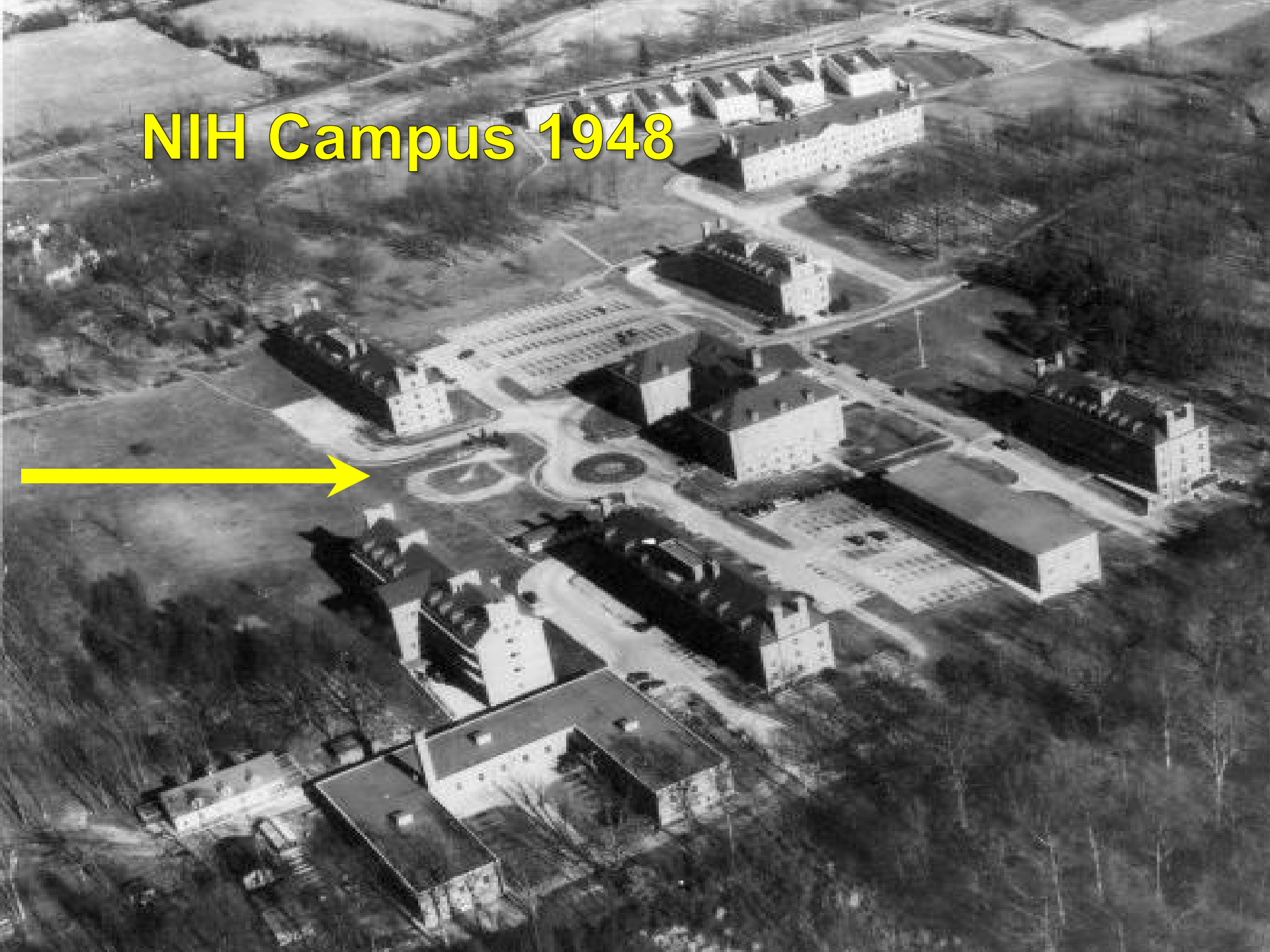
Impact of Medical Research on U.S. Health

- Cancer: rates down ~1% per year; each 1% drop saves ~$500 billion
- Cardiovascular disease: deaths down > 60% in the last half-century
- HIV therapies: people living to 70+
- Life expectancy gains worth ~$3.2 trillion annually
- Cost of sequencing the genome is ~$1K, compared to $400M for the Human Genome Project

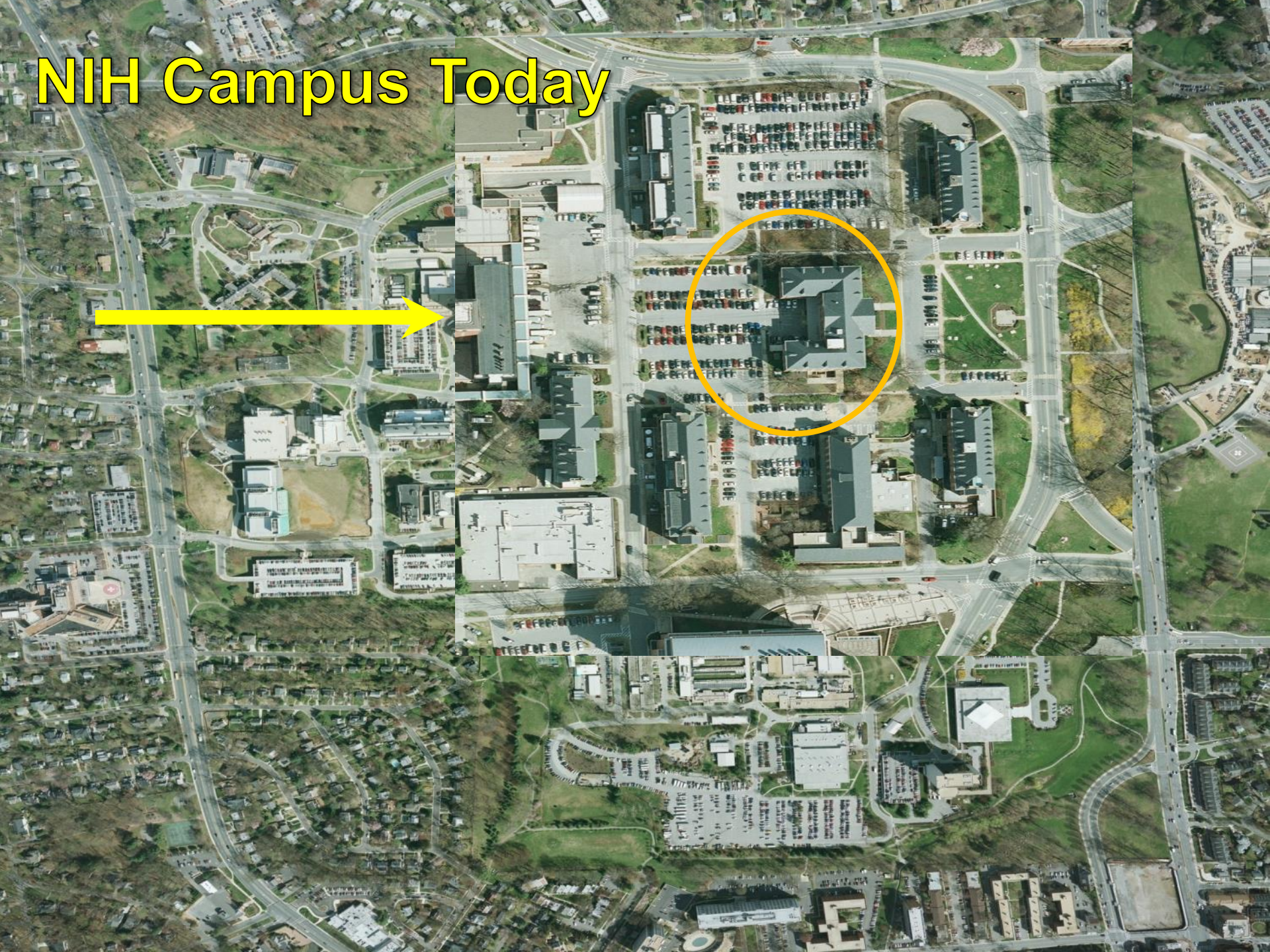
U.S. Life Expectancy



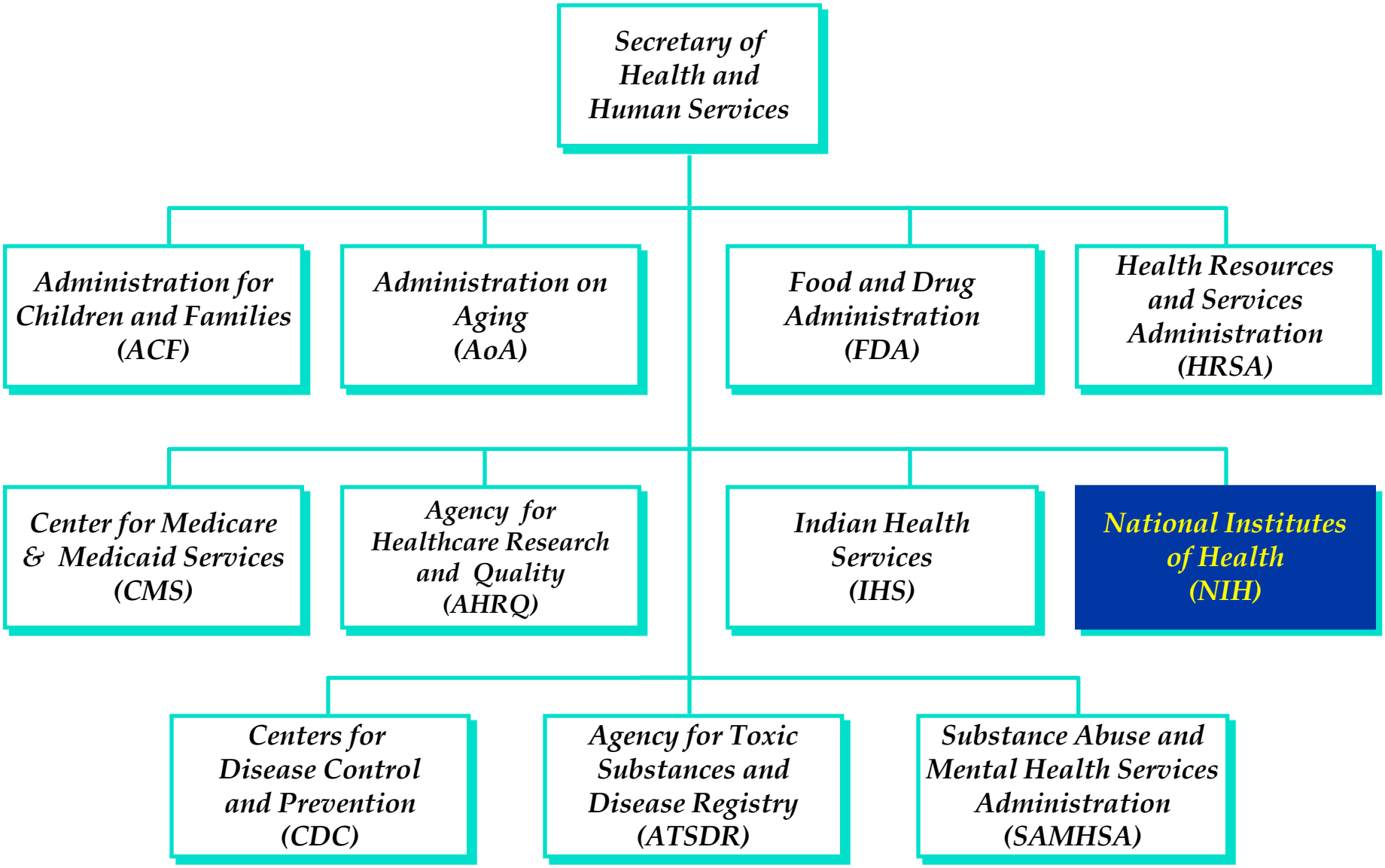

Birthplace of the NIH: 1887
Marine Hospital -- Staten Island, NY


NIH Campus 1948

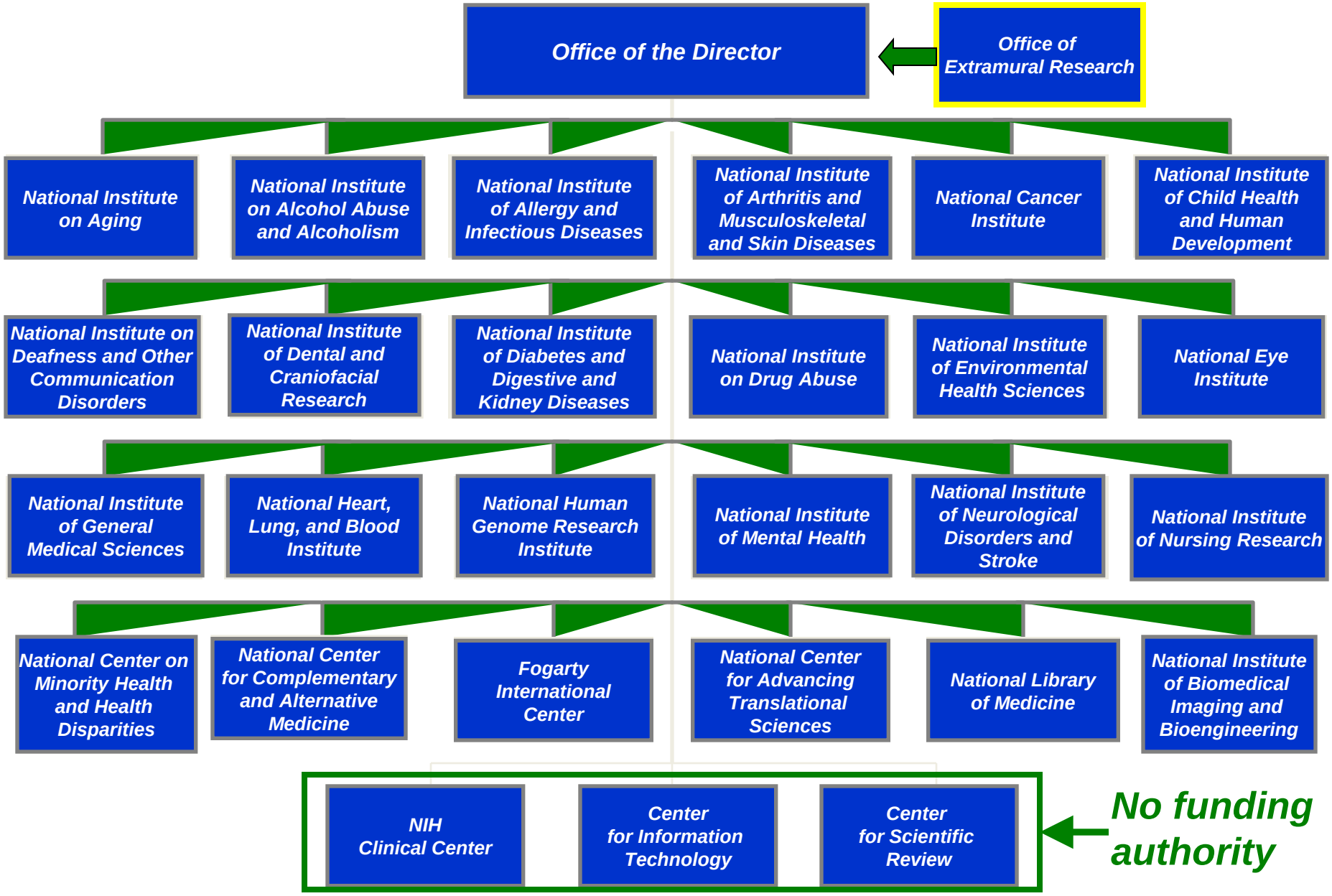
NIH Campus Today



U.S. Dept. of Health & Human Services



National Institutes of Health



Understanding the Dual Nature of NIH

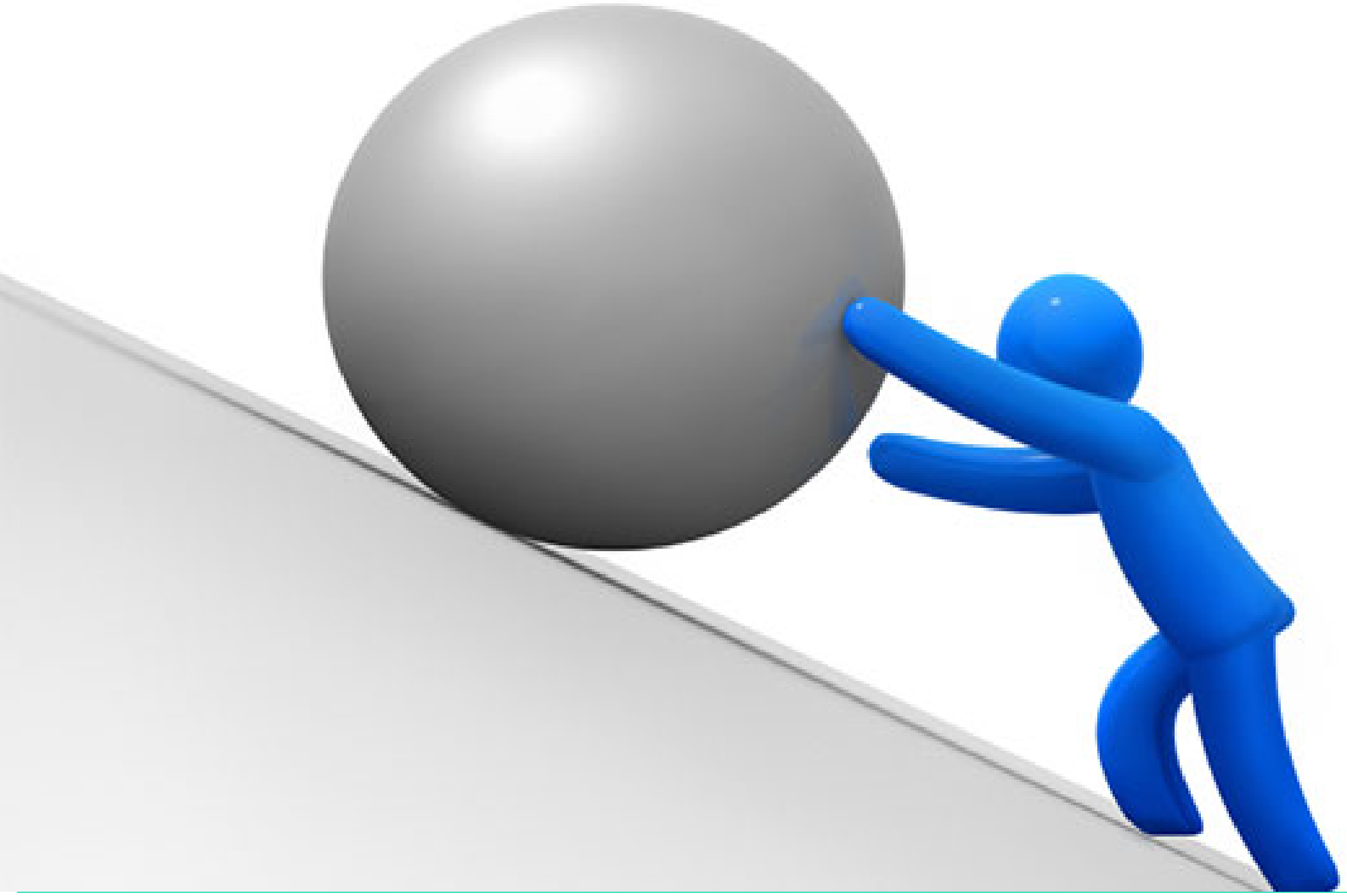
NIH *is* an institution
(Intramural Research)

- Approx. 6,000 scientists
- Approx. 11% of NIH's budget

NIH *supports* institutions & people (Extramural Research)

- >2,500 institutions
- >400,000 scientists & research personnel
- Approx. 70,000 applications and 40,000 awards annually
- Approx. 81% of the NIH budget

Challenging times!!!!!



Clinical Review & Education

Special Communication | SCIENTIFIC DISCOVERY AND THE FUTURE OF MEDICINE

The Anatomy of Medical Research
US and International Comparisons

JAMA The Journal of the American Medical Association

Hamilton Moses III, MD; David H. M. Matheson, JD, MBA; Sarah Cairns-Smith, PhD; Benjamin P. George, MD, MPH; Chase Palisch, MPhil; E. Ray Dorsey, MD, MBA

Editorials pages 143 and 145

Supplemental content at jama.com

IMPORTANCE Medical research is a prerequisite of clinical advances, while health service research supports improved delivery, access, and cost. Few previous analyses have compared the United States with other developed countries.

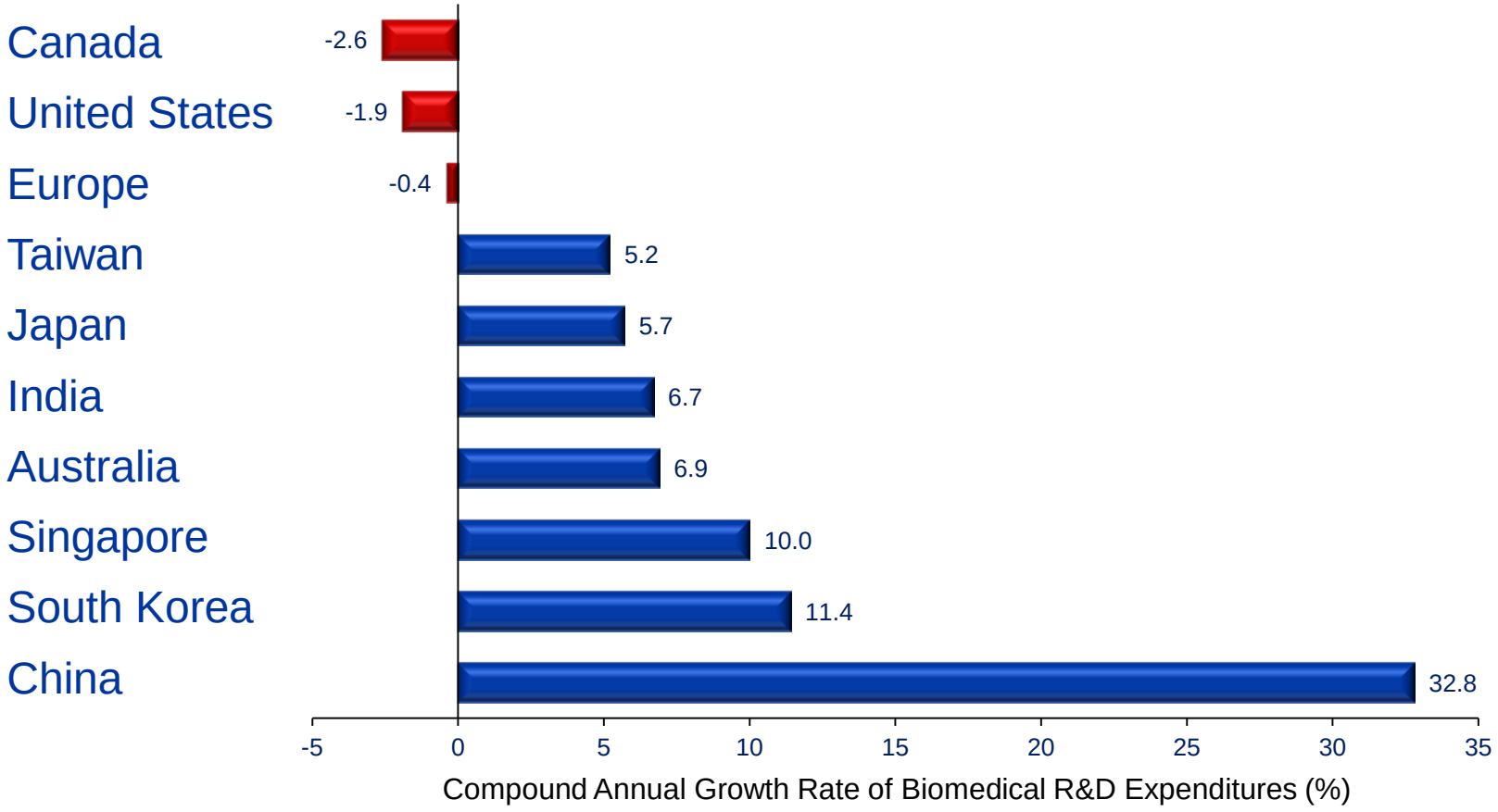
OBJECTIVES To quantify total public and priv
and to evaluate resulting patents, publicatio
(economic outputs).

EVIDENCE REVIEW Publicly available data from 1994 to 2012 were compiled showing trends in US and international research funding, productivity, and disease burden by source and industry type. Patents and publications (1981-2011) were evaluated using citation rates and impact factors.

FINDINGS (1) Reduced science investment: Total US funding increased 6% per year (1994-2004), but rate of growth declined to 0.8% per year (2004-2012), reaching $117 billion (4.5%) of total health care expenditures. Private sources increased from 46% (1994) to 58% (2012). Industry reduced early-stage research, favoring medical devices, bioengineered drugs, and late-stage clinical trials, particularly for cancer and rare diseases. National Insitutes of Health allocations correlate imperfectly with disease burden, with cancer and HIV/AIDS receiving disproportionate support. (2) Underfunding of service innovation: Health services research receives $5.0 billion (0.3% of total health care expenditures) or only 1/20th of

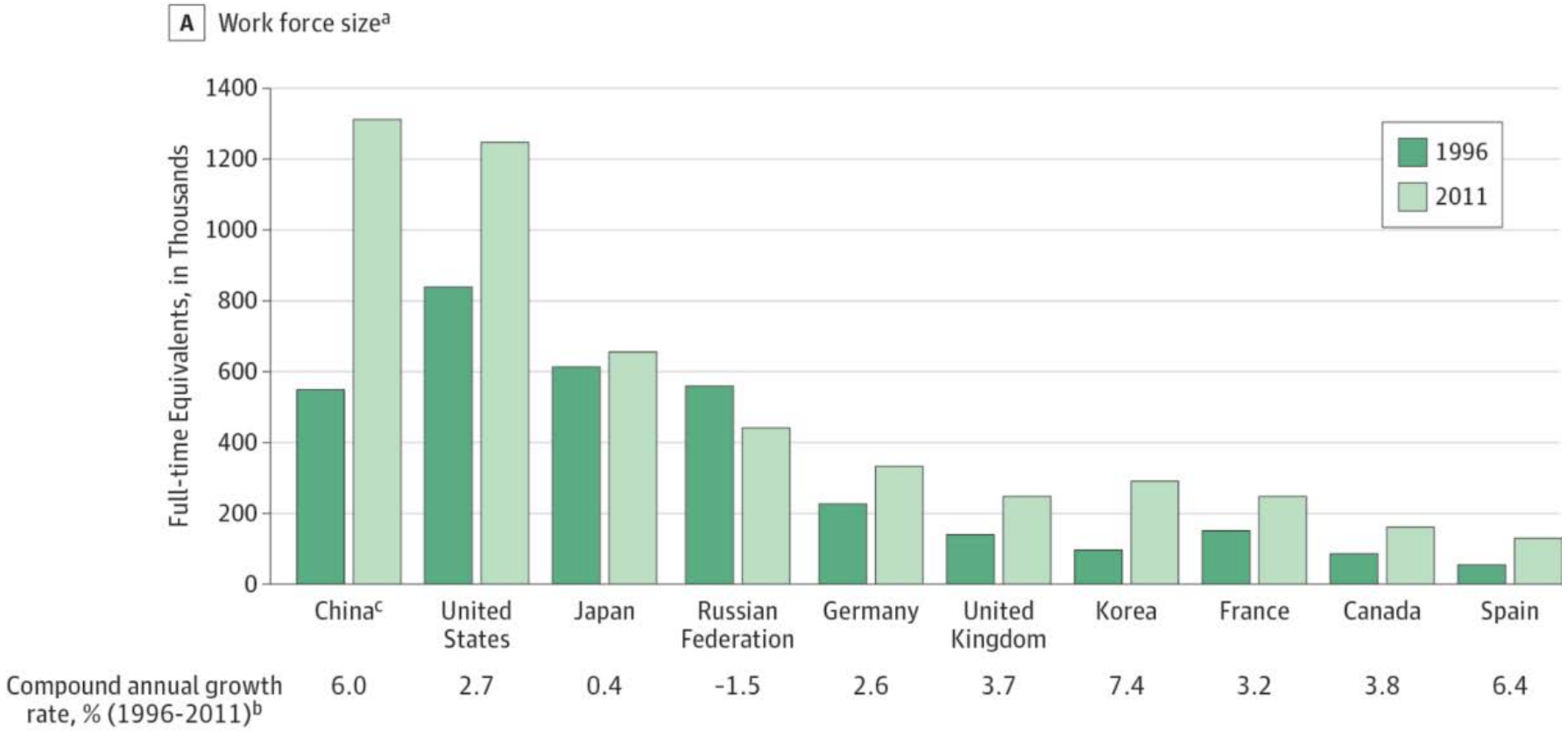
In 2004, the United States funded 57% of medical research worldwide. In 2011 that share declined to 44%.

Compound Annual Growth Rate of Biomedical R&D Expenditures by Country, Adjusted for Inflation 2007–2012



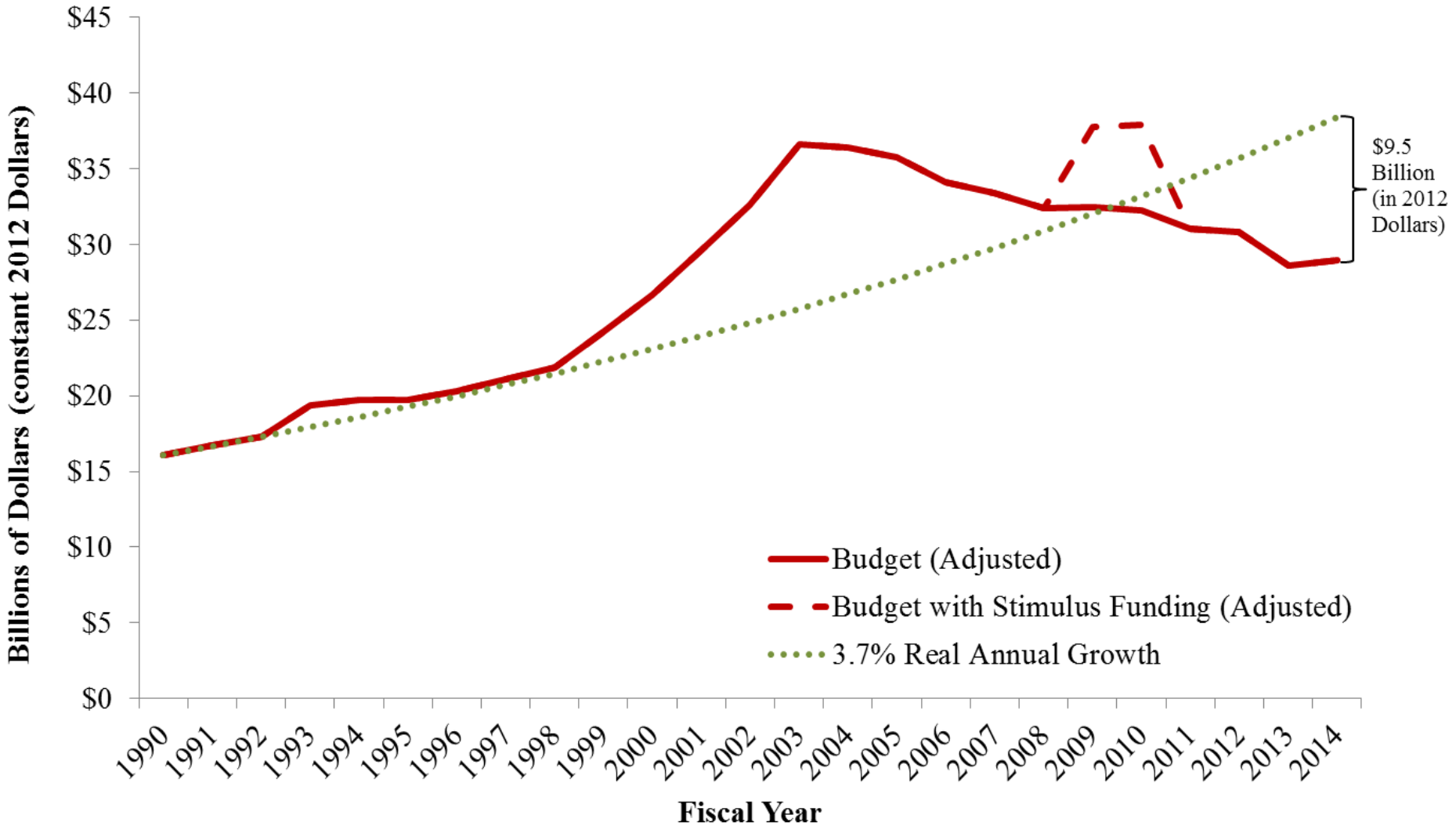
Source: N Engl J Med. 2014 Jan 2;370(1):3-6

Top 10 Countries by Size of Science and Technology Workforce, 1996-2011



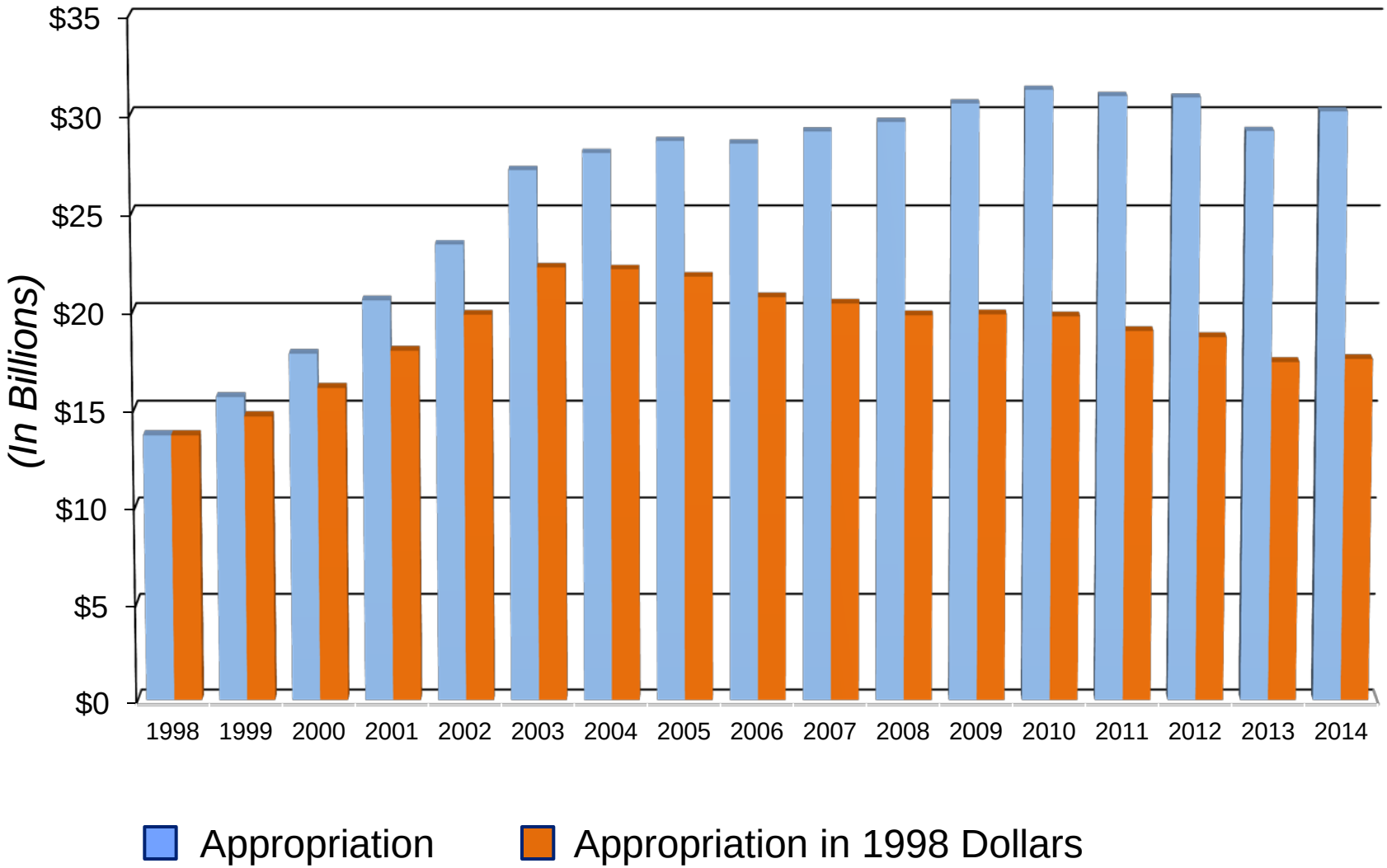
From: **The Anatomy of Medical Research: US and International Comparisons**
JAMA. 2015;313(2):174-189. doi:10.1001/jama.2014.15939

National Institutes of Health Funding
1990-2014

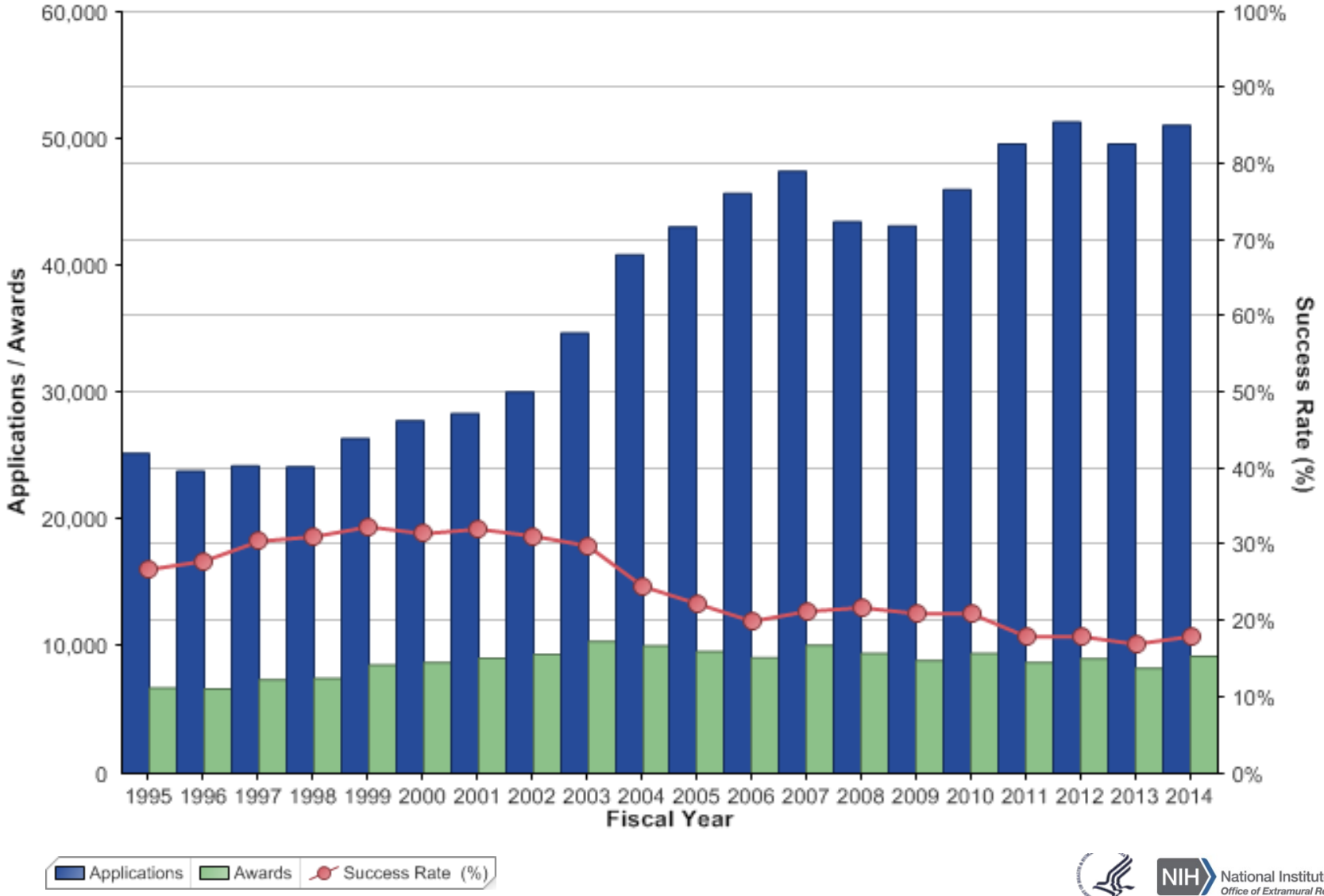


Note: The 3.7 % Real Annual Growth is based on average real growth between 1971 and 1997. Dollar values are adjusted to 2012 Dollars using the Biomedical Research and Development Price Index (BRDPI), http://officeofbudget.od.nih.gov/gbiPriceIndexes.html.
Source: NIH Office of Extramural Research and Office of Budget source data (March 29, 2014)

NIH Program Level in Nominal Dollars and Constant 1998 Dollars, FY1998 – FY2014



Research Project Grants: Competing Applications, Awards, and Success Rates



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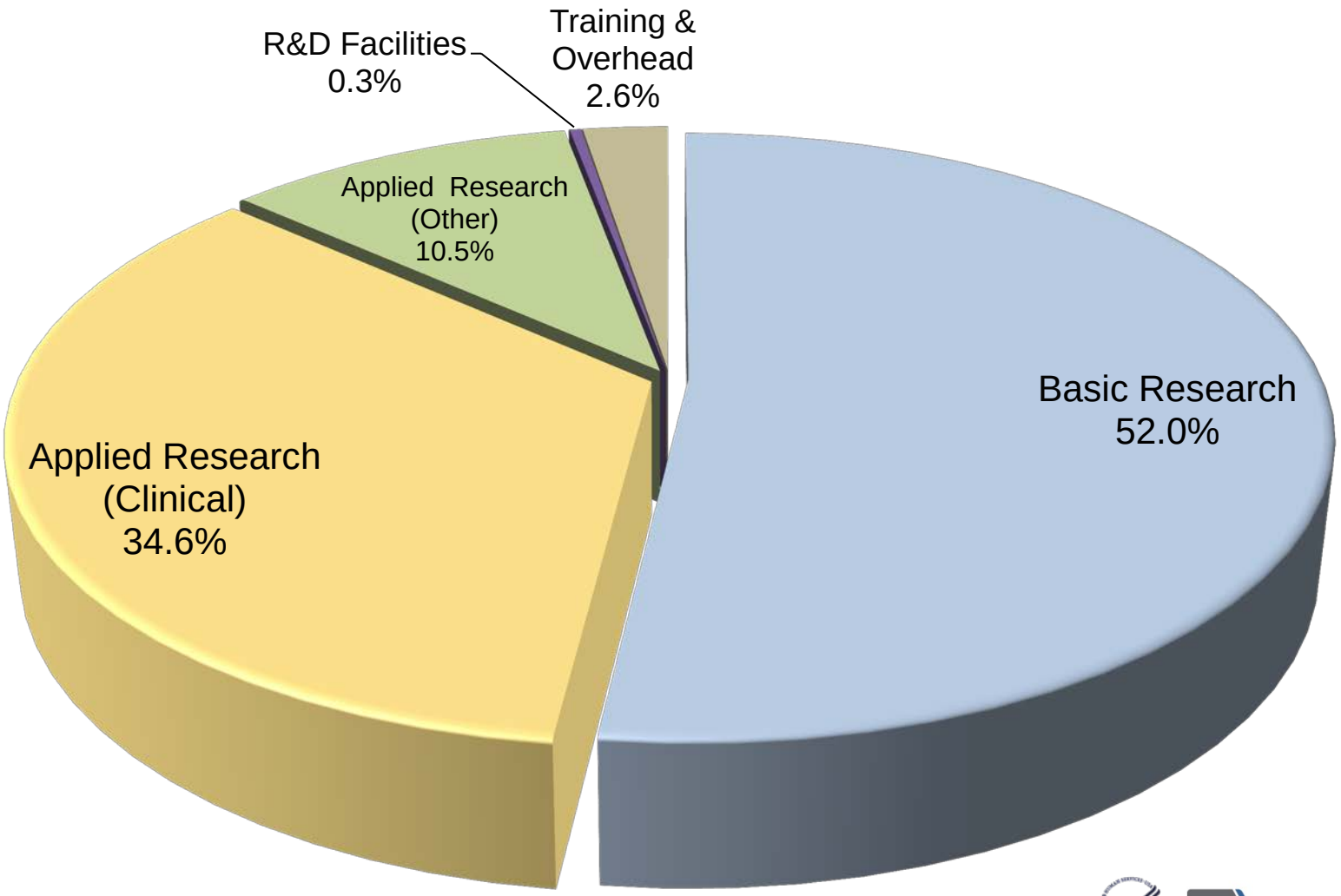
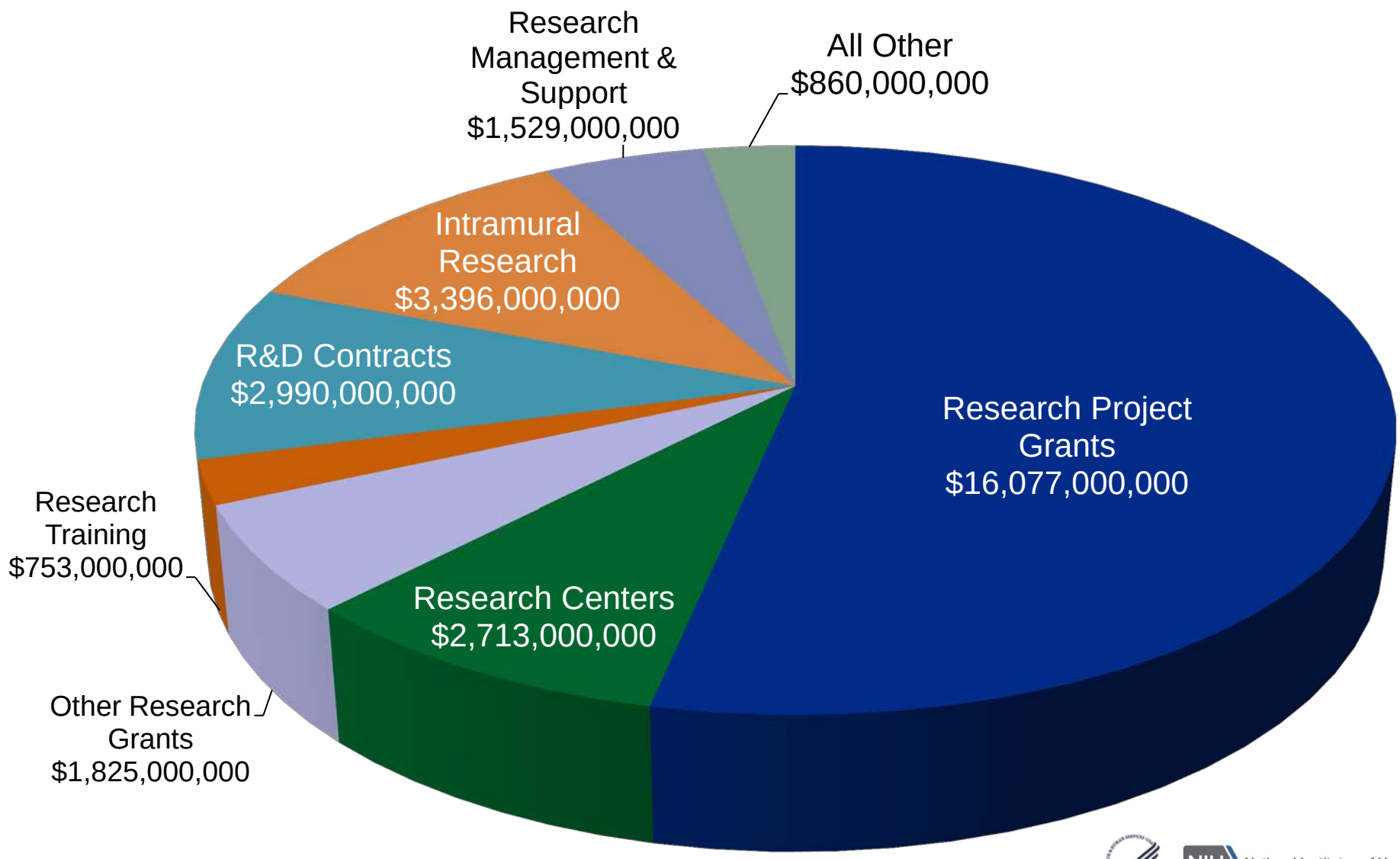
Distribution of NIH Funding for Basic and Clinical Research



NIH Budget Authority: FY 2014 Enacted



Rock Talk

Helping connect you with the NIH perspective

Posted on December 31, 2014 by Sally Rockey

2014 By the Numbers

Application and award summary data for fiscal year 2014 are now available in the NIH Data Book. These data are of particular interest for all of us this year, considering the historic low of the success rate last year, and the reduction of NIH's budget in fiscal year 2013, due to sequestration. For this reason, in the table below, we include both FY 2013 and FY 2012 data for comparison purposes.

We received 51,073 competing RPG applications at NIH in fiscal year 2014, an increase compared to last year, but still below the highest number of applications received by NIH in a fiscal year (51,313 applications in FY 2012). We'll continue to monitor this closely, to see if there is a true downward trend in incoming RPG applications, and to observe the effects of the new resubmission policy announced last April.

Looking at data across both competing and non-competing awards, the average size of RPGs

Dr. Sally Rockey is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

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FY 2014 by the Numbers: Research Applications, Funding, and Awards

	2013	2014
Number of RPG applications increased	49, 581	51,073
Number of RPG awards increased	8,310	9,241
Success rate of RPG applications increased	16.8%	18.1%
Average size of RPGs increased	$441,404	$472,827
Total amount of NIH funding that went to RPGs	$14,917,675,859	$15,635,912,476
Number of R01-equivalent applications decreased	28,044	27,502
Number of R01-equivalent awards increased	4,902	5,163
Success rate of R01-equivalent applications increased	17.5%	18.8%
Average size of R01-equivalent awards increased	$402,569	$427,083
Total amount of NIH funding that went to R01-equivalents	$10,075,486,256	$10,238,888,890

Program & Policy News

A broader context for ‘individualizing’ medical care to advance human health

NIH National Institutes of Health
Office of Extramural Research

“And that’s why the budget I send this Congress on Monday will include a new Precision Medicine Initiative that brings America closer to curing diseases like cancer and diabetes, and gives all of us access, potentially, to the personalized information that we need to keep ourselves and our families healthier.”

President Barack Obama
January 30, 2015

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Genomics

EHRs

Technologies

Data Science

Patient Partnerships

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Precision Medicine Initiative: The Vision

- **NEAR TERM**: Cancer as a Model of Precision Medicine
  - Leading edge of precision medicine, yet more to learn
  - Ramp up current efforts to include more cancer types
- **LONGER TERM**: Expanding the Model to Other Diseases
  - Create national research cohort of >1 million volunteers
  - Generate knowledge base for precision medicine
- **POLICY CHANGES**: Remove Barriers to Clinical Implementation
  - Update federal rules protecting research participants
  - Advance FDA oversight of precision medicine products




Precision Medicine Initiative: Proposed Fiscal Year 2016 Funding

Agency	$ Million
National Institutes of Health	$200
Food and Drug Administration	$10
Office of the National Coordinator for Health Information Technology	$5
TOTAL	$215

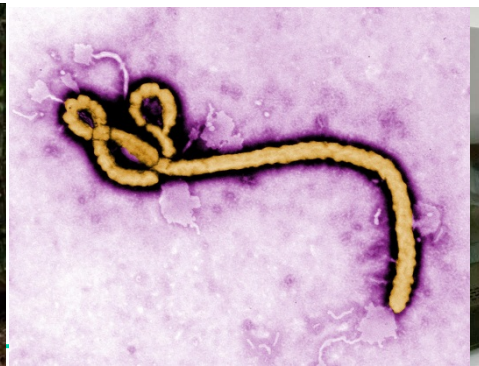
Ebola Virus Disease:
U.S. Government-Supported Research

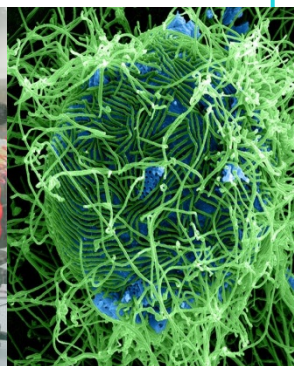
- Federal agencies collaborating to support development of Ebola vaccines and treatments
  - Department of Health and Human Services:
    - National Institutes of Health
    - Centers for Disease Control and Prevention
    - Food and Drug Administration
    - Biomedical Advanced Research & Development Authority
  - Department of Defense:
    - Walter Reed Army Institute of Research
    - Defense Threat Reduction Agency
    - U.S. Army Medical Research Institute of Infectious Diseases
- All working with USAID and new White House Ebola Response Coordinator, Ron Klain

NIH CDC FDA BARDA WRAIR Walter Reed Army Institute of Research Soldier Health • World Health USAMRIID United States Army Medical Research Institute of Infectious Diseases

Ebola Virus Disease: NIH Research

- Longstanding commitment to research on viral hemorrhagic fevers, including Ebola
- Two Ebola test vaccines appear safe in Partnership for Research on Ebola Vaccines in Liberia (PREVAIL) Phase 2/3 clinical trial
  - cAd3-EBOZ candidate vaccine: developed by NIAID and GlaxoSmithKline
  - VSV-ZEBOV candidate vaccine: developed by Public Health Agency of Canada and licensed to NewLink Genetics Corporation and Merck
- Z-Mapp (NIH/Mapp Biopharmaceutical)
  - Three highly purified monoclonal antibodies
  - Two disrupt fusion to the cell (possible then to reduce to one)
  - One binds to the spike protein to alert immune system
- Patients treated at the NIH Clinical Center



BRAIN Initiative
“The Next Great American Project”

Learning the Language of the Brain

NIH National Institutes of Health
Office of Extramural Research

FY 2014 Investments

Government Agencies	$ in Millions
National Institutes of Health	**$40 .7**
• *Blueprint for Neuroscience Research*	*$10M*
• *NIMH*	*$12.85M*
• *NINDS*	*$12.85M*
• *NIDA*	*$4M*
• *NIBIB*	*$1M*
Defense Advanced Research Projects Agency	**$50**
National Science Foundation	**$20**
Food and Drug Administration	**N/A**

HHMI HOWARD HUGHES MEDICAL INSTITUTE

THE KAVLI FOUNDATION

+ Private Investments

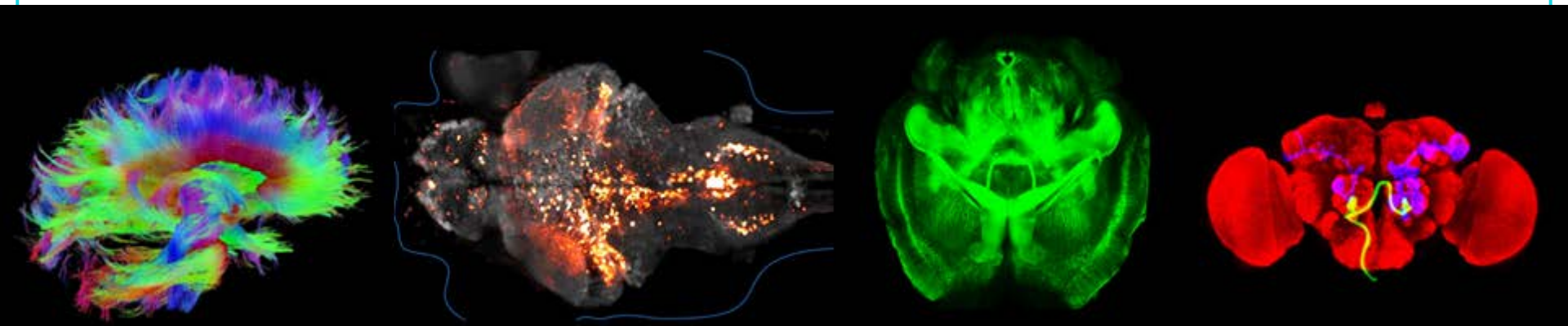
ALLEN INSTITUTE for BRAIN SCIENCE *Fueling Discovery*

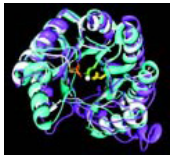
SIMONS FOUNDATION

NIH National Institutes of Health *Office of Extramural Research*

Unraveling Life's Mysteries through Basic Research: The BRAIN Initiative

- September 30: NIH's first investment in a 12-year scientific vision; awarded $46M to more than 100 researchers in 15 states and 3 nations
- Among the 58 projects are efforts to:
  - Develop innovative technologies to advance basic neuroscience
  - Generate methods for classifying the brain's diverse cells/circuits
  - Create/optimize technologies for recording and modulating groups of cells that act together in circuits
  - Form interdisciplinary teams to develop new non-invasive tools for human brain imaging





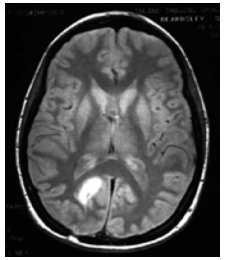
NIH Bioengineering Program Areas

Biomaterials

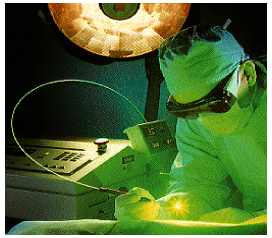
Biomedical Informatics

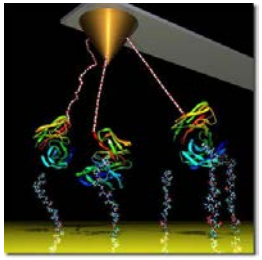
Sensors

Image-Guided Interventions



Micro-biomechanics



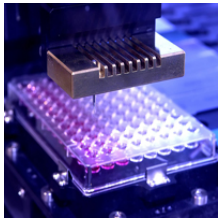


Integration of Implantable Medical Devices

MRI & Spectroscopy

Tissue Engineering

Nuclear Medicine

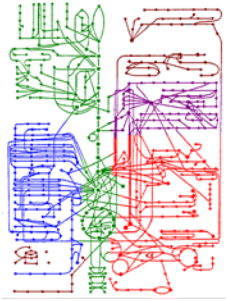


Micro- & Nano-Systems

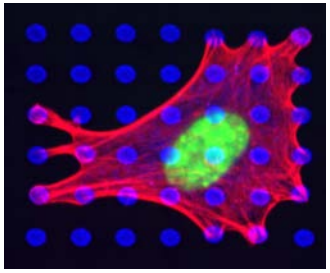
Rehab Engineering

Molecular Imaging

Ultrasound



Drug & Gene Delivery Systems & Devices



Optical Imaging & Spectroscopy

And much more!

U.S. Department of Health & Human Services | National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering

Creating Biomedical Technologies to Improve Health

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Sensor technology helps clinicians improve breast exam skills

Advances in Cancer Surgery: Making Tumors Glow

2015 DEBUT Contest Announced

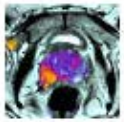
NIBIB launches "Want to Be a Bioengineer?" game app

NIBIB News & Highlights

Engineering a Revolutionary Medical School
April 3, 2015

New Treatment for Scaffold Creates Healthier Engineered Bladder Tissue
March 18, 2015

NIH announces Follow that Cell Challenge finalists
March 16, 2015



New Imaging Technique for Improved Prostate Cancer Detection and Treatment
March 9, 2015

Funding Opportunities

Lifespan Human Connectome Project: Baby Connectome (U01)

NIBIB Research Education Programs for

Scientific Program Areas

Rehabilitation Engi

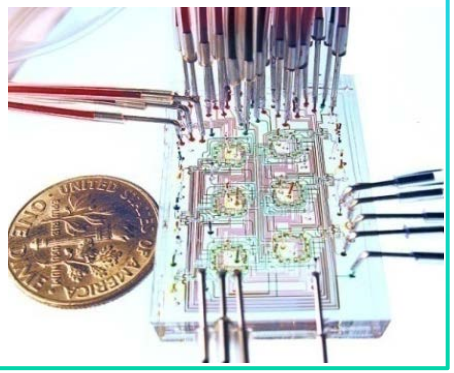
Optical Imaging and Spectroscopy

The newest of the NIH research Institutes and Centers—the mission of the National Institute of Biomedical Imaging and Bioengineering is to improve health by leading the development and accelerating the application of biomedical technologies.

NIH Bioengineering Program Announcements

- **PAR-14-092: Bioengineering Research Partnerships (BRP) [R01]** are appropriate for large teams tackling biomedical problems where an appropriate solution is developed using intermediate milestones and will result in a specific end-goal that can be reached within 5-10 years.
- **PAR-13-137: Bioengineering Research Grants (BRG [R01])** are for single investigators or small teams applying an integrative approach to an open-ended research question.
- **PA-12-284 : Exploratory/Developmental (R21) Bioengineering Research Grants (EBRG)** support early and conceptual stages of new exploratory and developmental research that may involve considerable risk but may lead to a breakthroughs

FAQs: http://www.nibib.nih.gov/funding/funding-policies/bioengineering-research-partnerships/FAQ



Investing in Innovation: SBIR/STTR Funding

http://sbir.nih.gov

SBIR/STTR Program Overview

- **Small Business Innovation Research (SBIR) Program:** Set-aside program for small business concerns to engage in Federal R&D -- with potential for commercialization.
- **Small Business Technology Transfer (STTR) Program:** Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions -- with potential for commercialization.
- **Total SBIR/STTR FY 2015 allocation: $786M**

NIH SBIR/STTR 3-Phase Program

Discovery

Phase I

Phase I Feasibility Study

Budget Guide: $150K for SBIR and STTR
Project Period: 6 months (SBIR); 1 year (STTR)

Development

Phase II

Phase II Full Research/R&D

$1M for SBIR and STTR, over two years

Phase IIB

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/Tools to FDA
Many, but not all, IC's participate
Varies~$1M per year; up to 3 years

Commercial-ization

Phase III

Phase III Commercialization Stage

NIH, generally, not the "customer"
Consider partnering and exit strategy early

Rock Talk

Helping connect you with the NIH perspective

Posted on February 7, 2014 by Sally Rockey

Looking at Reproducibility

Many of you may have seen the recent *Nature* Commentary by NIH Director Francis Collins and NIH Deputy Director Larry Tabak that talks about how NIH is addressing concerns about reproducibility in science. If you haven't I'd encourage you to take a look.

The topic of reproducibility is not new, and there are a number of NIH institutes and offices that have completed or are embarking on projects that contribute to the goal of improving rigor in the design and methods used in research. In addition, NIH has a number of programs and policies that more generally support the goals of reproducibility, for example, PubMed Commons, data sharing and public access policies, and more.

Improving the reproducibility of biomedical science is critical to NIH's mission. Feedback from the community on these pilot projects will inform us about the approaches to adopt and implement agency-wide. So stay involved and stay tuned…there will be more to follow.

Dr. Sally Rockey is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

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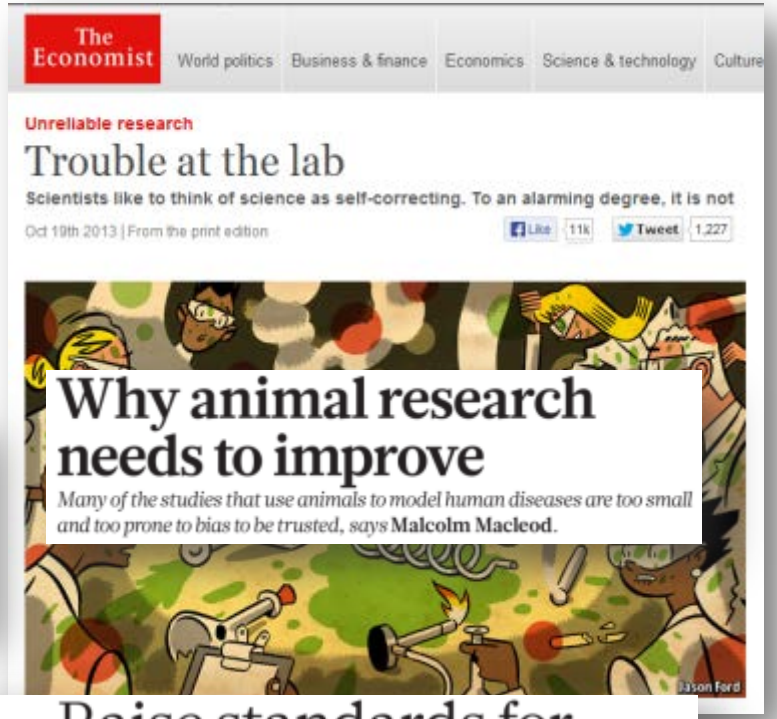
The Growing Challenge

- Noted by research community; in multiple publications

- [illegible]arch areas

- precl[illegible]


The Economist

World politics | Business & finance | Economics | Science & technology | Culture

Unreliable research

Trouble at the lab

Scientists like to think of science as self-correcting. To an alarming degree, it is not

Oct 19th 2013 | From the print edition

Like 11k Tweet 1,227

Why animal research needs to improve

Many of the studies that use animals to model human diseases are too small and too prone to bias to be trusted, says **Malcolm Macleod**.

Jason Ford

Beware the creeping cracks of bias

Evidence is mounting that research is riddled [illegible] unchecked, this could erode public trust, warn

Believe it or not: how much can we rely on published data on potential drug targets?

Florian Prinz, Thomas Schlange and Khusru Asadullah

False-Positive Psychology: Undisclosed Flexibility in Data Collection and Analysis Allows Presenting Anything as Significant

Raise standards for preclinical cancer research

C. Glenn Begley and **Lee M. Ellis** propose how methods, publications and incentives must change if patients are to benefit.

Drug targets slip-sliding away

The starting point for many drug discovery programs is a published report on a new drug target. Assessing the reliability of such papers requires a nuanced [illegible]

Reforming Science: Methodological and Cultural Reforms

PERSPECTIVE

doi:10.1038/nature11556

A call for transparent reporting to optimize the predictive value of preclinical research

Story C. Landis[1], Susan G. Amara[2], Khusru Asadullah[3], Chris P. Austin[4], Robi Blumenstein[5], Eileen W. Bradley[6], Ronald G. Crystal[7], Robert B. Darnell[8], Robert J. Ferrante[9], Howard Fillit[10], Robert Finkelstein[1], Marc Fisher[11], Howard E. Gendelman[12], Robert M. Golub[13], John L. Goudreau[14], Robert A. Gross[15], Amelie K. Gubitz[1], Sharon E. Hesterlee[16], David W. Howells[17], John Huguenard[18], Katrina Kelner[19], Walter Koroshetz[1], Dimitri Krainc[20], Stanley E. Lazic[21], Michael S. Levine[22], Malcolm R. Macleod[23], John M. McCall[24], Richard T. Moxley III[25], Kalyani Narasimhan[26], Linda J. Noble[27], Steve Perrin[28], John D. Porter[1], Oswald Steward[29], Ellis Unger[30], Ursula Utz[1] & Shai D. Silberberg[1]

The US National Institute of Neurological Disorders and Stroke convened major stakeholders in June 2012 to discuss how to improve the methodological reporting of animal studies in grant applications and publications. The main workshop recommendation is that at a minimum studies should report on sample-size estimation, whether and how animals were randomized, whether investigators were blind to the treatment, and the handling of data. We recognize that achieving a meaningful improvement in the quality of reporting will require a concerted effort by investigators, reviewers, funding agencies and journal editors. Requiring better reporting of animal studies will raise awareness of the importance of rigorous study design to accelerate scientific progress.

Possible Causes for Difficulties Reproducing Data

- Poor experimental design: e.g., no blinding, randomization, insufficient power, variable experimental conditions, insufficient documentation of methods
- Errors in analysis & interpretation: lack of replication, inappropriate use of statistics, misinterpretation of findings
- Inadequate reporting of: detailed methods, failures to replicate, exclusion of outliers, changes to endpoints
- Overemphasis on the “exciting” or “big picture” finding sometimes results in publications leaving out necessary details of experiments performed
- Difficulty in publication of “negative” findings
- Underlying issues of poor training in experimental design and perverse reward incentives

Good Experimental Design (and Reporting) Underlies Rigor and Reproducibility of Findings

"There's a flaw in your experimental design. All the mice are scorpios."

Five requirements for a "good" experimental design:

- Be unbiased
- Have high precision
- Have a wide range of applicability
- Be simple
- Have the ability to calculate uncertainty

COX, D.R. *Planning Experiments*, John Wiley and Sons, New York, 1958.

NIH plans to enhance reproducibility

Francis S. Collins and **Lawrence A. Tabak** discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

A growing chorus of concern, from scientists and laypeople, contends that the complex system for ensuring the reproducibility of biomedical research is failing and is in need of restructuring[1,2]. As leaders of the US National Institutes of Health (NIH), we share this concern and here explore some of the significant interventions that we are planning.

Science has long been regarded as 'self-correcting', given that it is founded on the replication of prior work. Over the long term, that principle remains true. In the shorter term

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Services pursued only 12 such cases[3]. Even if this represents only a fraction of the actual problem, such papers are vastly

> *"Efforts by the NIH alone will not be sufficient to effect real change in this unhealthy environment."*

Rock Talk

Helping connect you with the NIH perspective

Posted on May 16, 2014 by Sally Rockey

More on Addressing Sex Differences in Pre-clinical Studies

You likely saw the recent Nature policy article, in which NIH Director Francis Collins and NIH Office of Research on Women's Health Director Janine Clayton discussed ways that NIH is addressing sex differences in research. As our understanding of science evolves, so do our policies that govern research. This commentary cites several studies that highlight the need to further consider sex differences in preclinical research and describes how NIH will enact new policies to expand the consideration of sex differences in research studies using animal models and cells. The article generated quite a buzz in the community, and I wanted to take this opportunity to explain the roll out of our implementation plan.

As you saw in the article, we stated that we will begin phasing in policies over the course of the next fiscal year (which begins October 1st), requiring grantees to address inclusion of both

Dr. Sally Rockey is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

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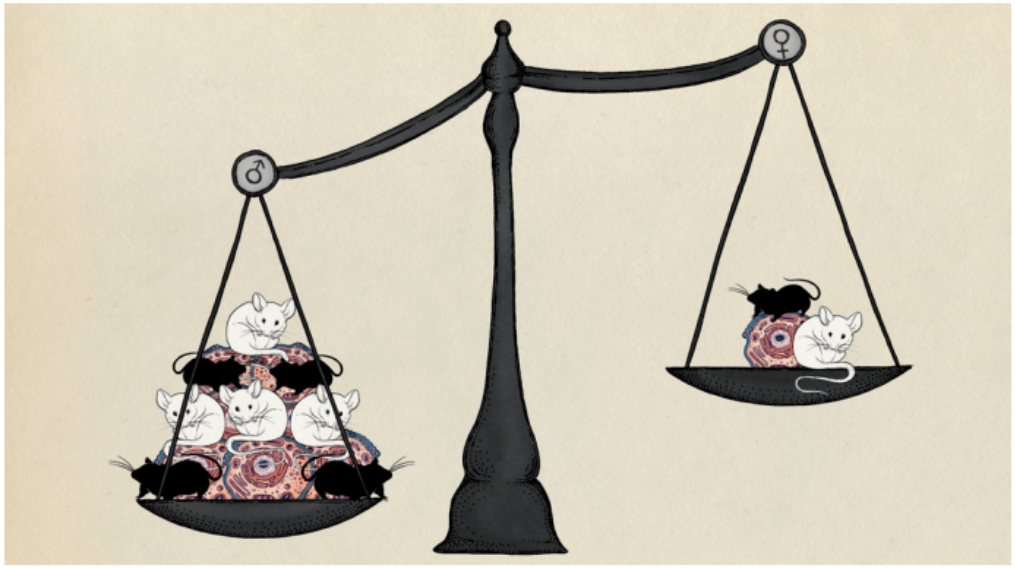


ILLUSTRATION BY KARIE SCOTT

NIH to balance sex in cell and animal studies

Janine A. Clayton and **Francis S. Collins** unveil policies to ensure that preclinical research funded by the US National Institutes of Health considers females and males.

More than two decades ago, the US National Institutes of Health (NIH) established the Office of Research on Women's Health (ORWH). At that time, the Congressional Caucus for Women's Issues, women's health advocacy groups and NIH scientists and leaders agreed that excluding women from clinical research was bad for women and bad for science. In 1993, the NIH Revitalization Act required the inclusion of women in NIH-funded clinical research.

Today, just over half of NIH-funded clinical-research participants are women. We know much more about the role of sex and gender in medicine, such as that low-dose aspirin has different preventive effects in women and men, and that drugs such as calls to action[1]. Publications often continue to neglect sex-based considerations and analyses in preclinical studies[2,3]. Reviewers, for the most part, are not attuned to this failure. The over-reliance on male animals and cells in preclinical research obscures key sex differences that could guide clinical studies. And it might be harmful: women experience higher rates of adverse drug reactions than men do[4]. Furthermore, inadequate inclusion of female cells and animals in experiments and inadequate analysis of data by sex may well contribute to the troubling rise of irreproducibility in preclinical biomedical research, which the NIH is now actively working to address[5,6].

The NIH plans to address the issue of sex and gender inclusion across biomedical research multi-dimen- stakeholders including publishers. This move is essential, potentially very powerful and need not be difficult or costly.

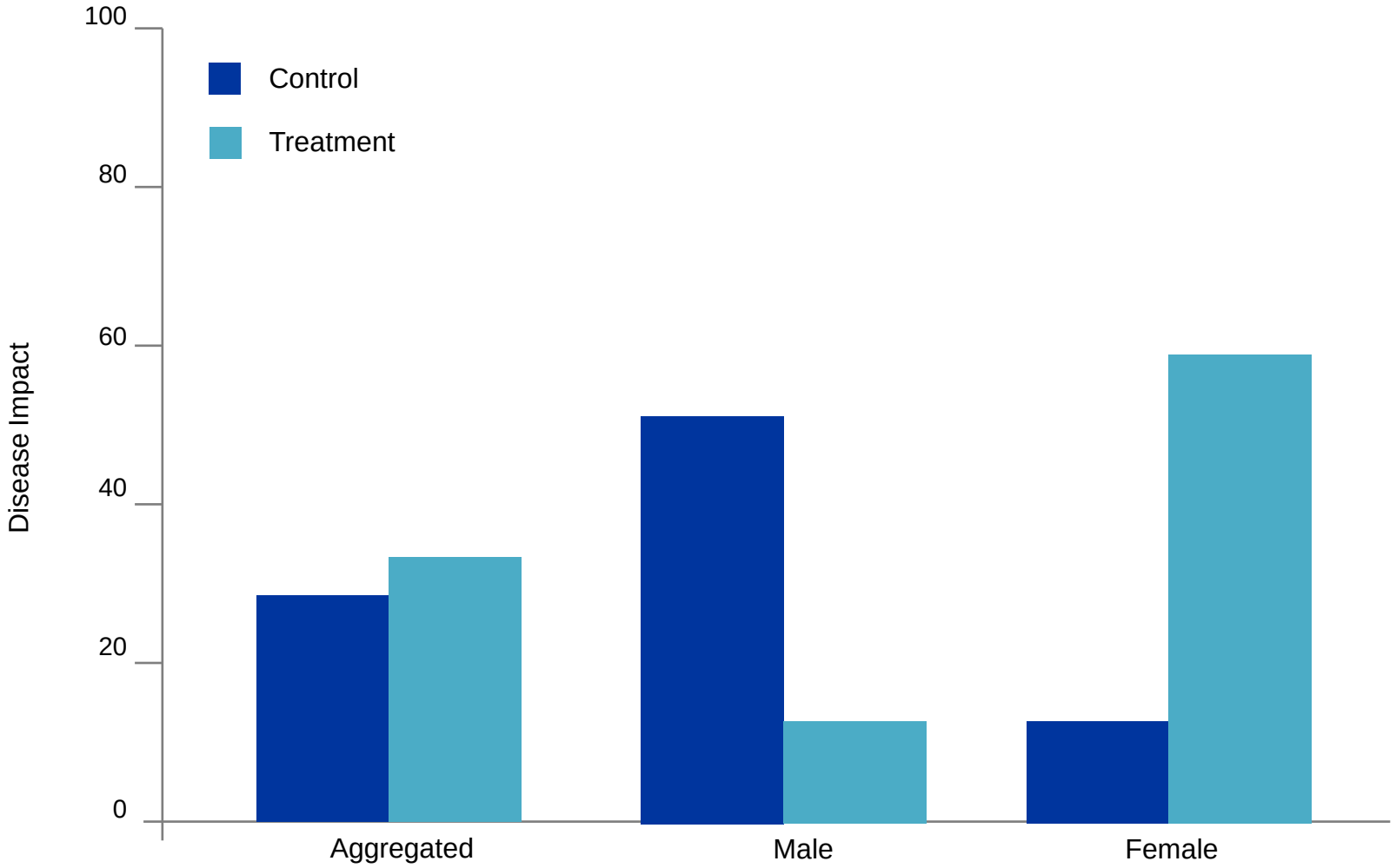
BETTER WITH BOTH

Certain rigorous studies evaluating the effects of sex differences have been effective in bridging the divide between animal and human work. One example concerns multiple sclerosis (MS). Women are more susceptible to MS than men are, but develop less-severe forms of the disease. The most widely accepted MS animal model — rodent experimental autoimmune encephalomyelitis (EAE) — has revealed[7] that sex differences in MS are related to both reproductive and non-reproductive factors. Findings[8] that oestrogen therapy provided benefits in rodent EAE

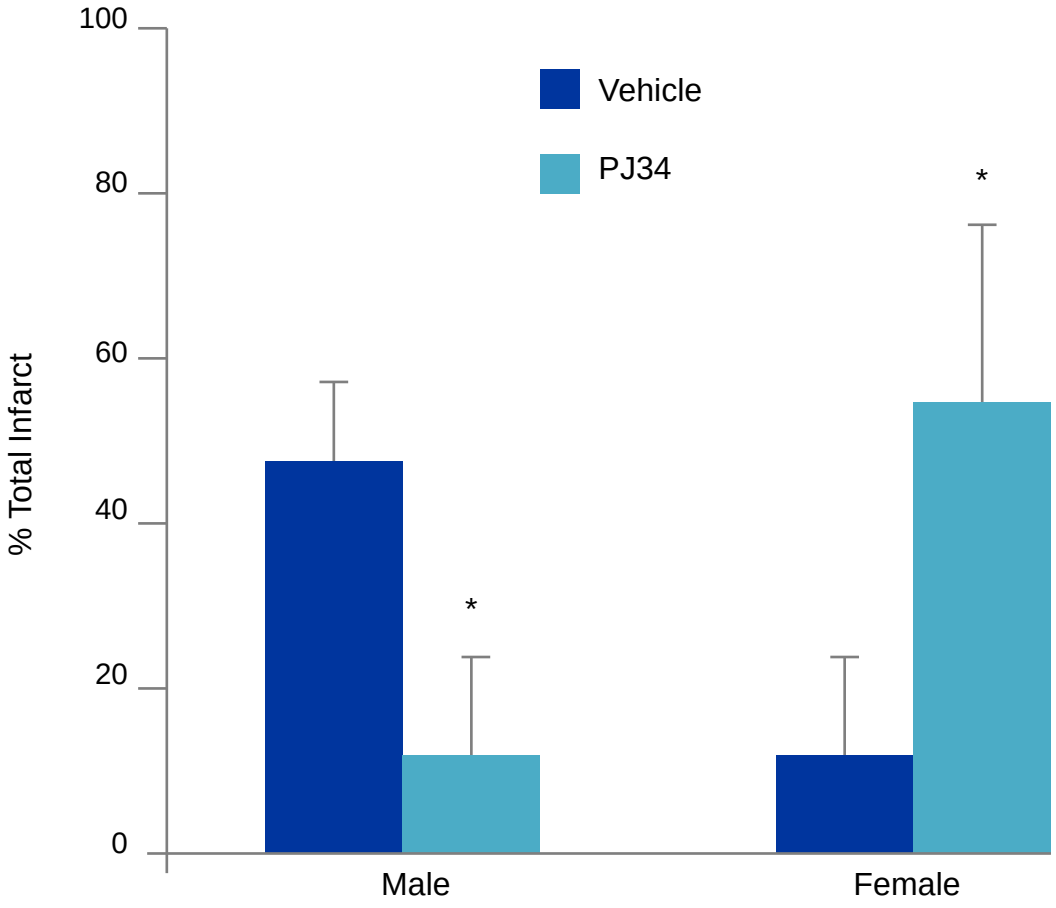
"Over the course of FY 2015, NIH plans to roll out policies that will require applicants to address inclusion of both sexes in biomedical research."

NIH National Institutes of Health
Office of Extramural Research

Biological/Disease Impact of Experimental Design



Real Life



The effects of the selective poly-ADP ribose polymerase (PARP-1) inhibitor PJ-34 in wild-type (WT) mice of both genders. Treatment with PJ-34 at ischemic onset reduced total infarction in male mice compared with saline-treated controls (* $P<0.001$). A significant increase in ischemic damage was seen in PJ-34-treated females compared with control (* $P<0.001$).

McCullough LD, et al. *Journal of Cerebral Blood Flow & Metabolism* (2005) **25,** 502–512.

Trans-NIH Actions

- Discussing reproducibility and transparency of research findings with stakeholder communities, such as journal editors
- Creating a new training module on research integrity and experimental design
- Implementing pilot studies to address key concerns, such as:
  - Developing a checklist to ensure more systematic evaluation of grant applications
  - Determining approaches needed to reduce “perverse incentives,” e.g., longer term support for investigators
  - Supporting replication studies
- Considering approaches to encourage applicants to:
  - Authenticate cell lines and other unique research resources
  - Analyze and report sex differences in preclinical research

NIH Application Resubmission Policy

- **NIH Guide Notice (NOT-OD-14-074)**
  NIH and AHRQ Announce Updated Policy for Application Submission, April 17, 2014

- "Effective immediately, the NIH and AHRQ will accept a new (A0) application following an unsuccessful resubmission (A1) application. The subsequent new application need not demonstrate substantial changes in scientific direction compared to previously reviewed submissions, and must not contain an introduction to respond to the critiques from the previous review."

New Biographical Sketch (Biosketch) Format in NIH Applications

- See Guide Notice: NOT-OD-15-032
- Required for applications submitted for due dates on or after May 25, 2015
- The new format allow researchers to:
  - Describe the magnitude and significance of their scientific contributions (including publications)
  - Provide more detailed information about their research experience in the context of the proposed project
- Science Experts Network Curriculum Vitae (SciENcv) will allow you to enter your biographical data once and convert it into biosketches that can be used for NIH or NSF grant applications and annual progress reports.

Rock Talk

Helping connect you with the NIH perspective

Posted on August 30, 2013 by Sally Rockey

Keeping Up With the Biomedical Research Workforce Initiative

Over the past two years I've frequently discussed the recommendations from the NIH Advisory Committee to the NIH Director (ACD) on the Biomedical Research Workforce. I know there's been loads of information coming from us about how we are implementing these recommendations. I'm happy to share our new website that compiles all of this biomedical workforce initiative information.

You can read about the background of the task force, and track progress for the seven main implementation areas. We include links to the relevant NIH Guide policy notices and funding opportunities for the activities resulting from task force recommendations, and timelines so that you can see when changes or new programs were announced, or are expected to take place.

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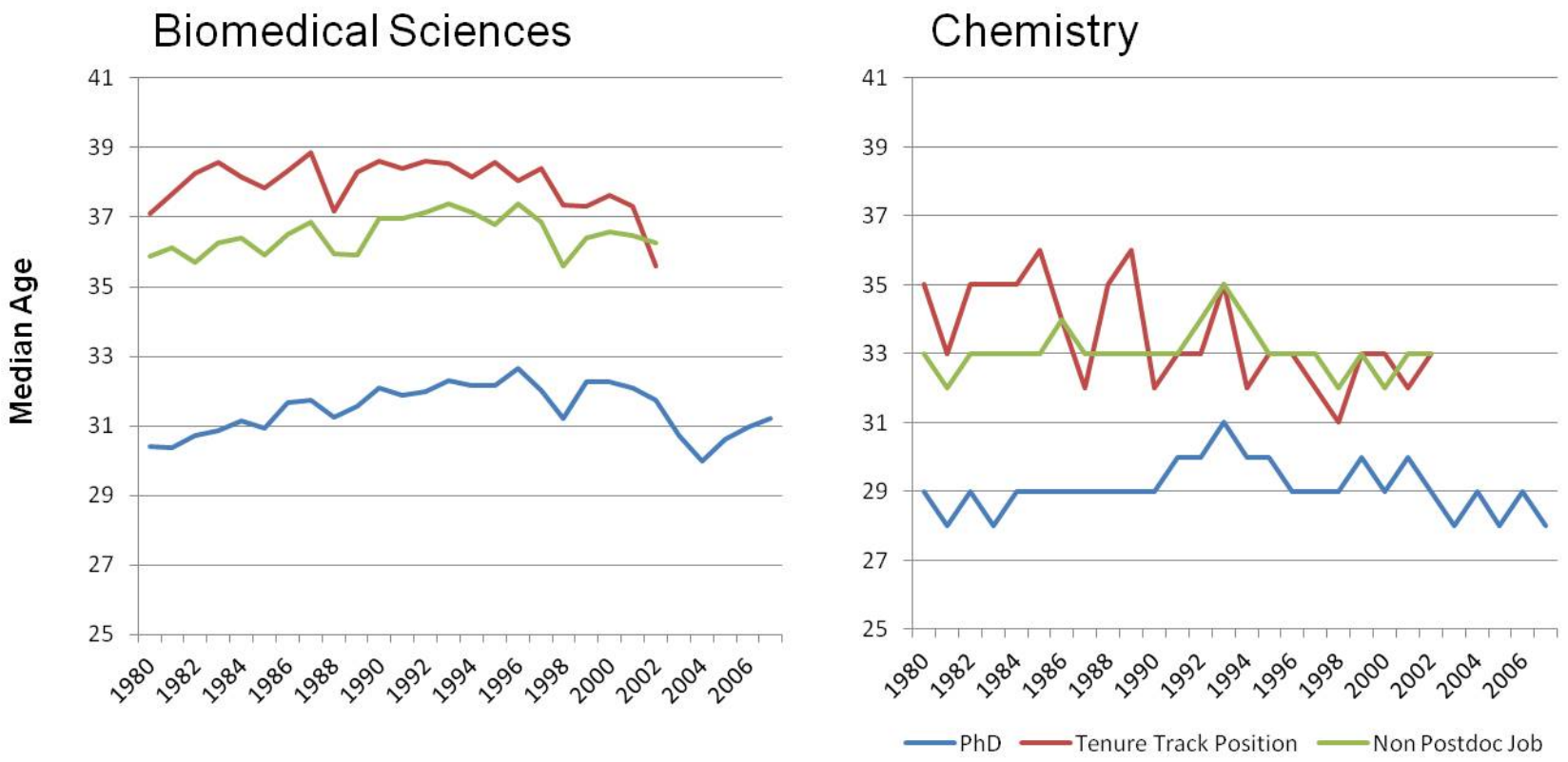
The Biomedical Research Workforce Working Group

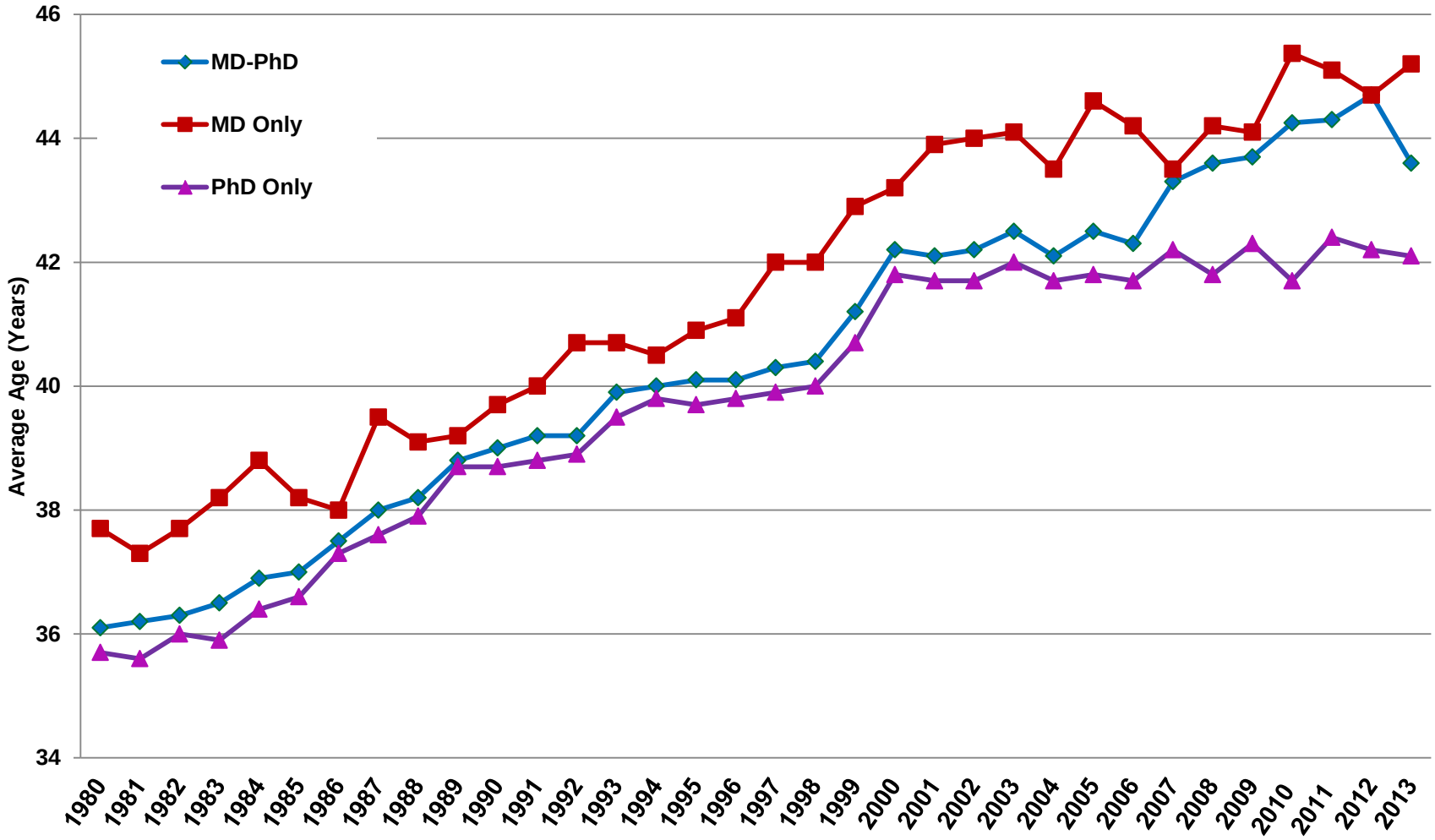
- A working group of the Advisory Committee to the NIH Director
- Charge: Develop a model for a sustainable and diverse U.S. biomedical research workforce that can inform decisions about training of the optimal number of people for the appropriate types of positions that will advance science and promote health.
- Based on this analysis and input from the extramural community, make recommendations for actions that NIH should take to support a future sustainable biomedical infrastructure.
- Reported to the ACD in June 2012.
  http://acd.od.nih.gov/Biomedical_research_wgreport.pdf
- Supplementary Web Site
  http://report.nih.gov/investigators_and_trainees/ACD_BWF

Age at First PhD, First Non Postdoctoral Job, First Tenure Track Job, for US trained Doctorates



Source: Survey of Earned Doctorates

Average Age and Degree Type of First-Time Investigators on R01-Equivalent Grants



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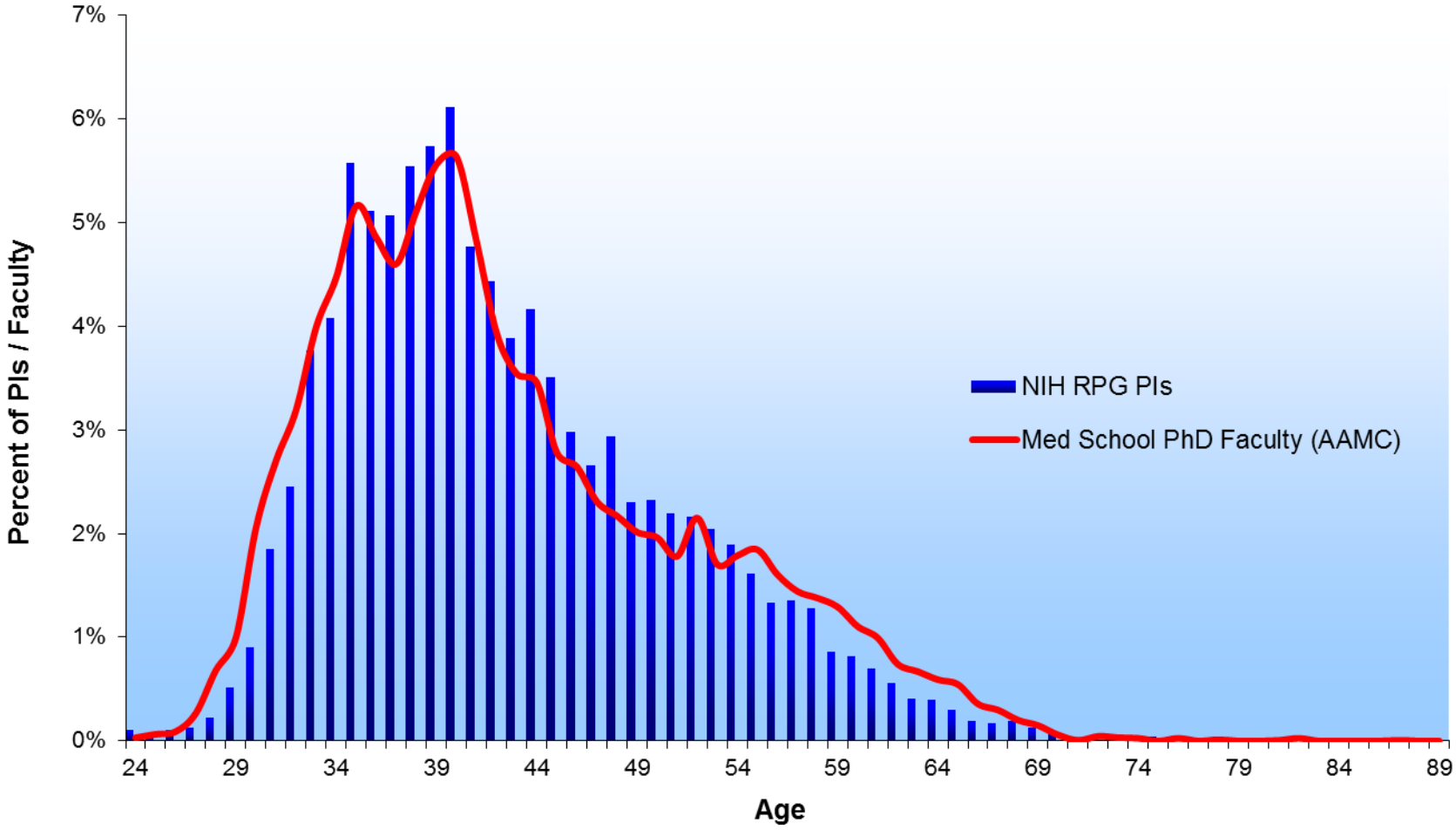
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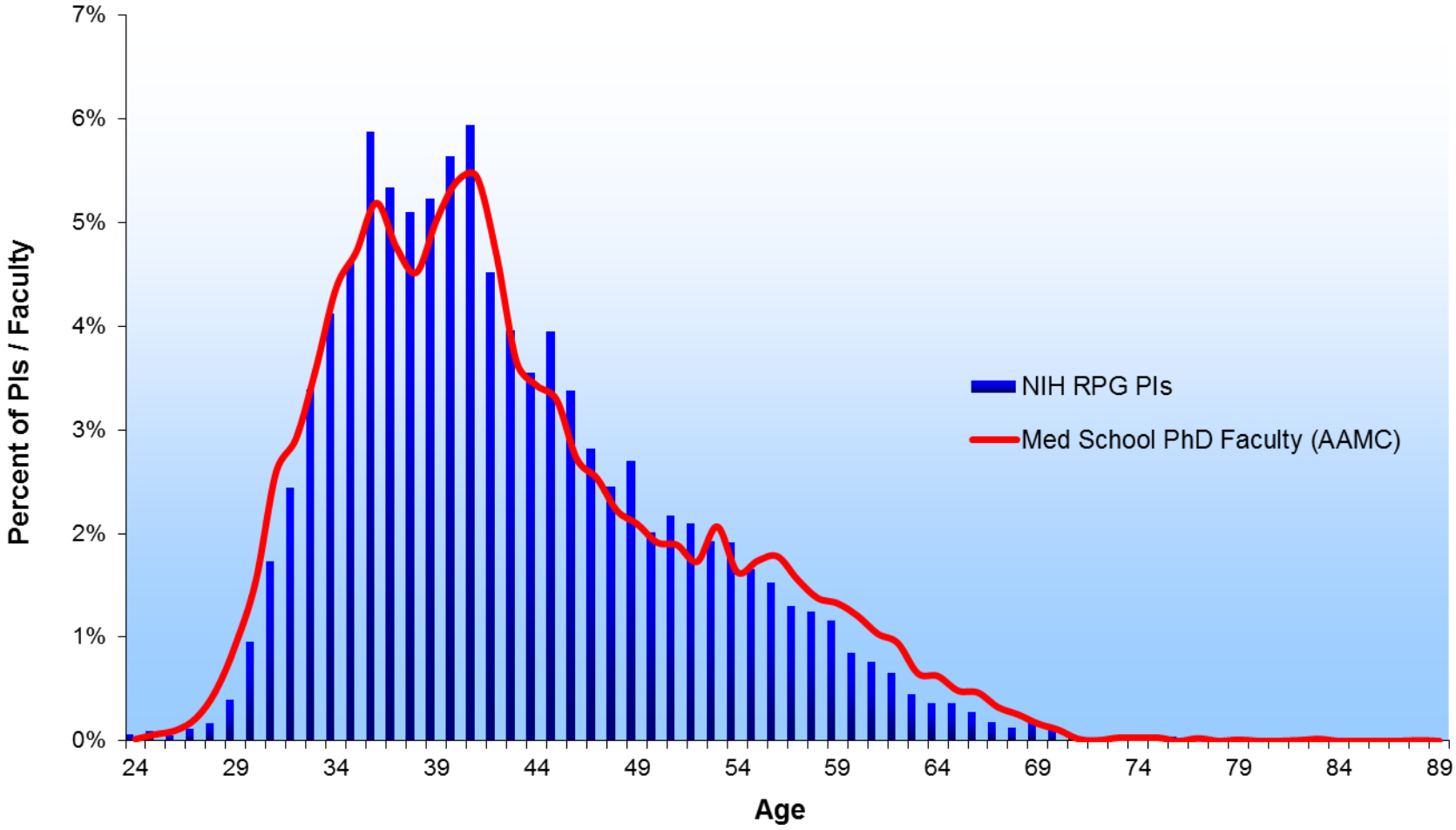

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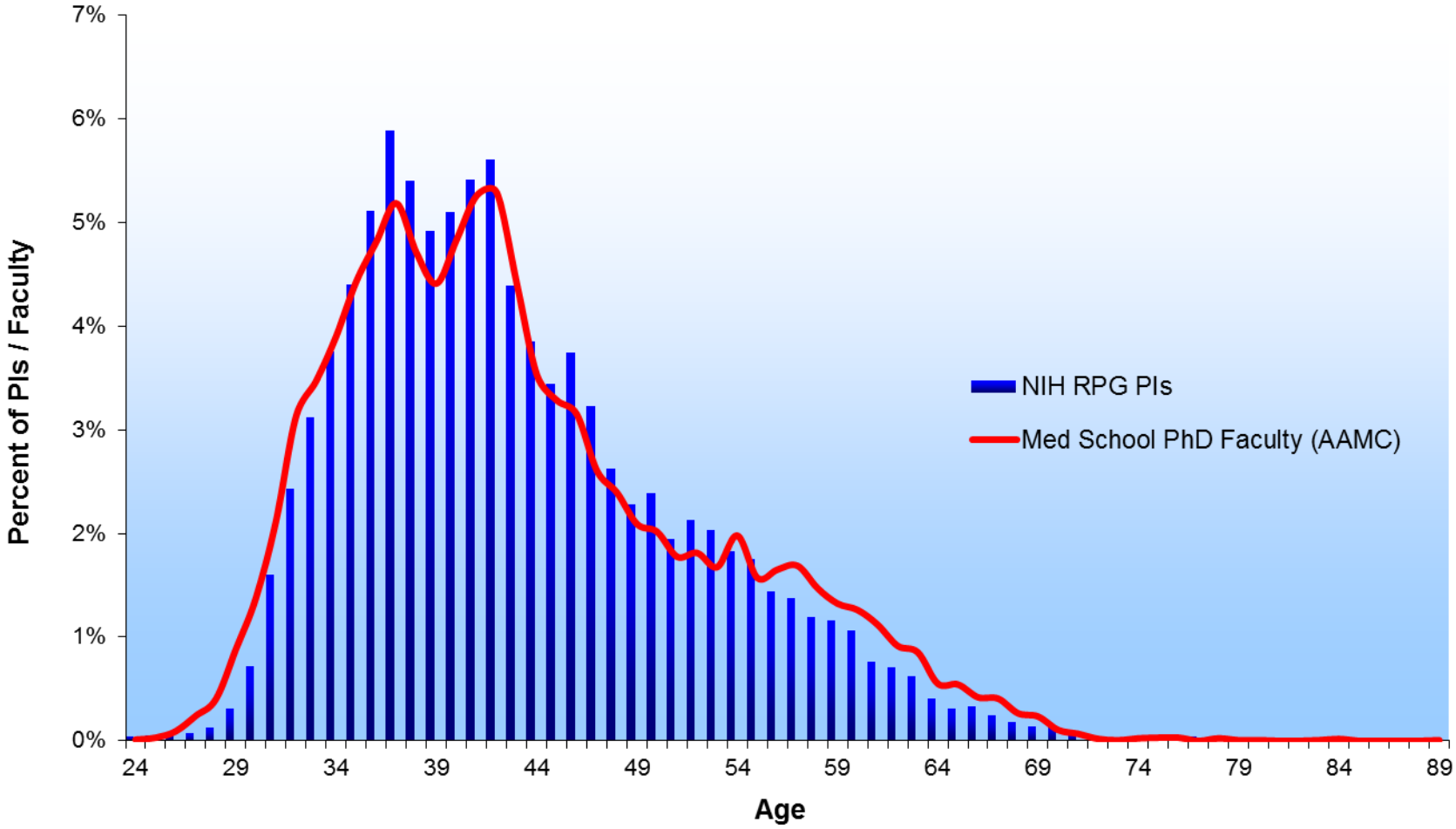
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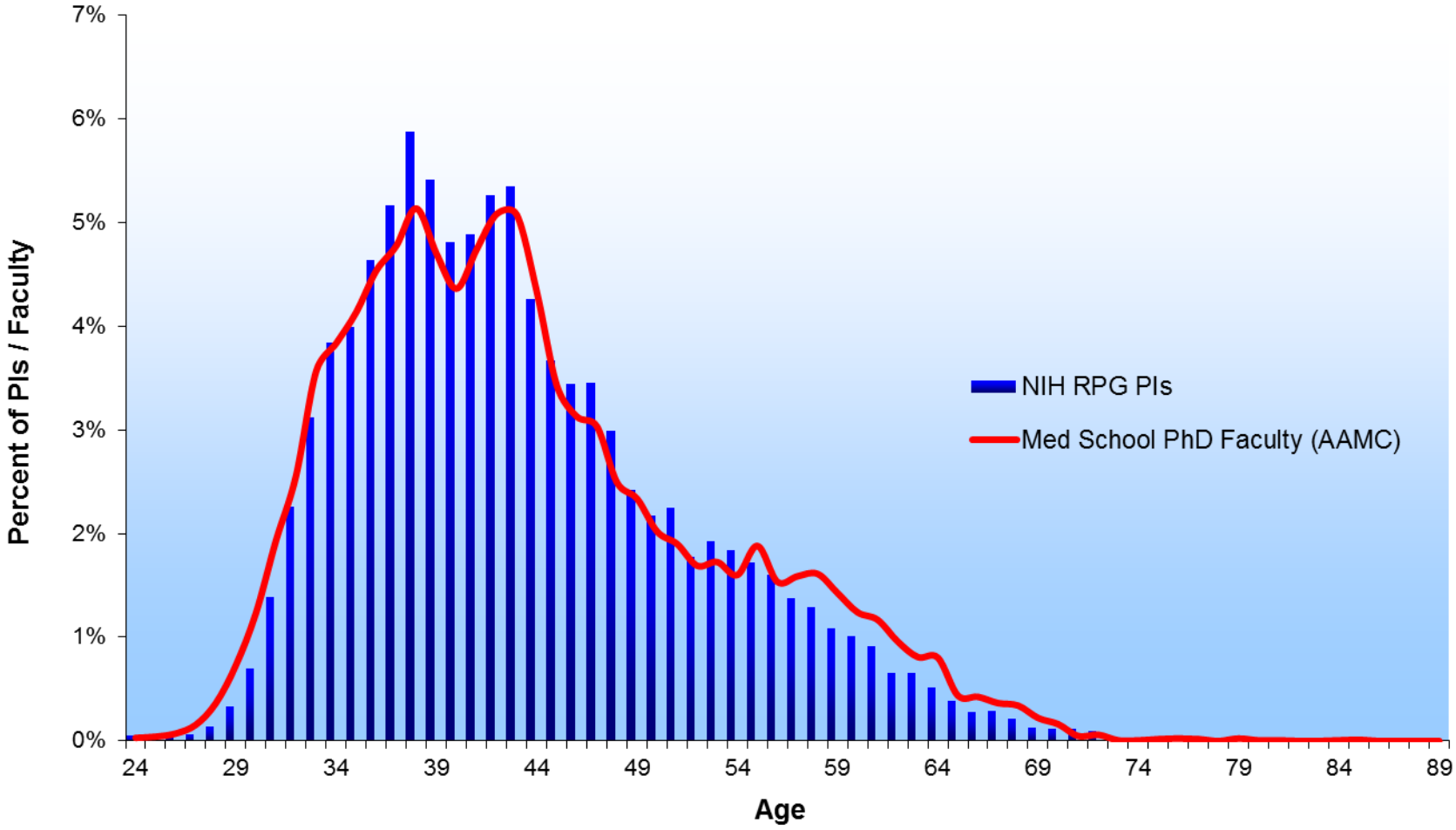
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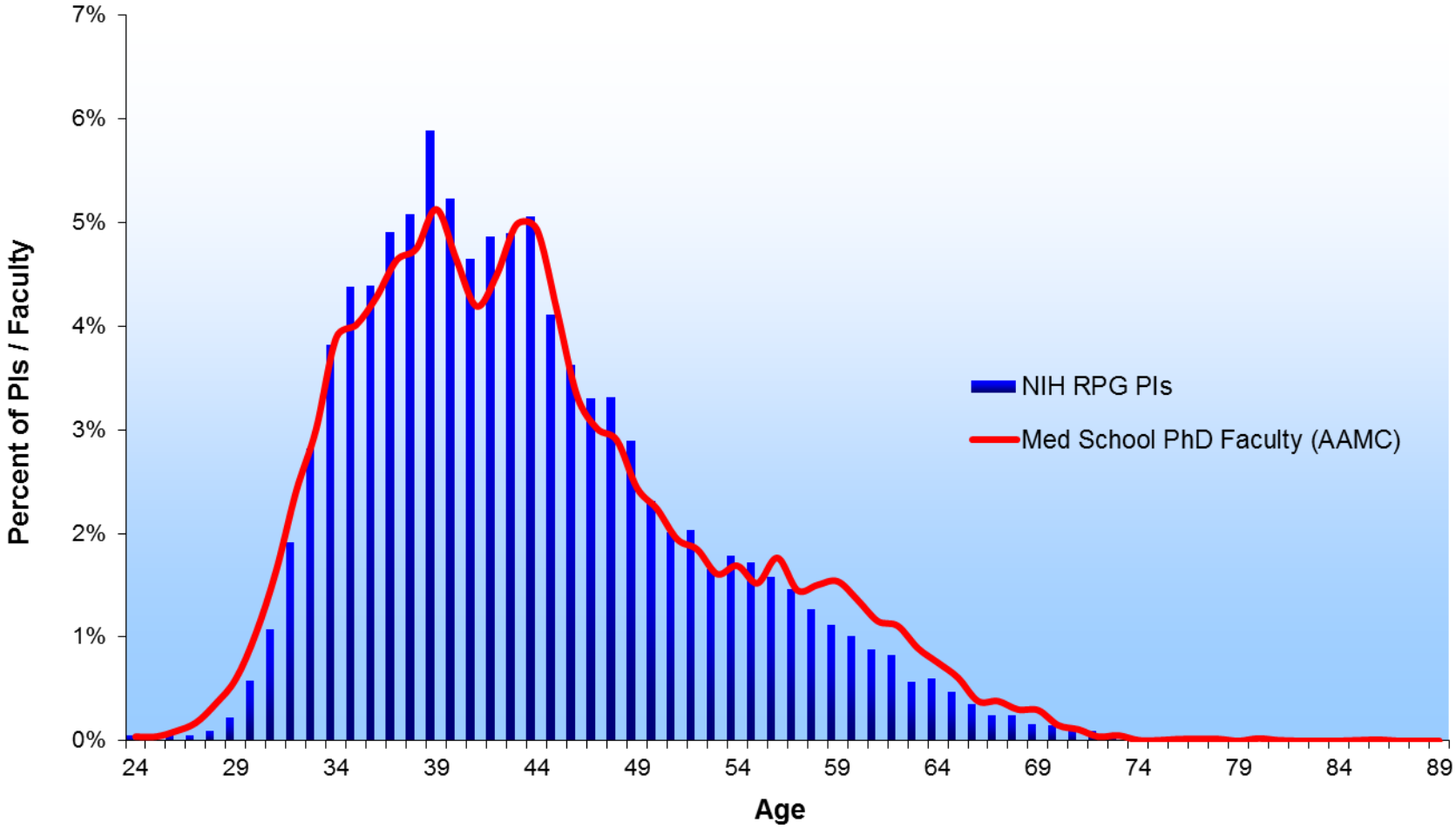
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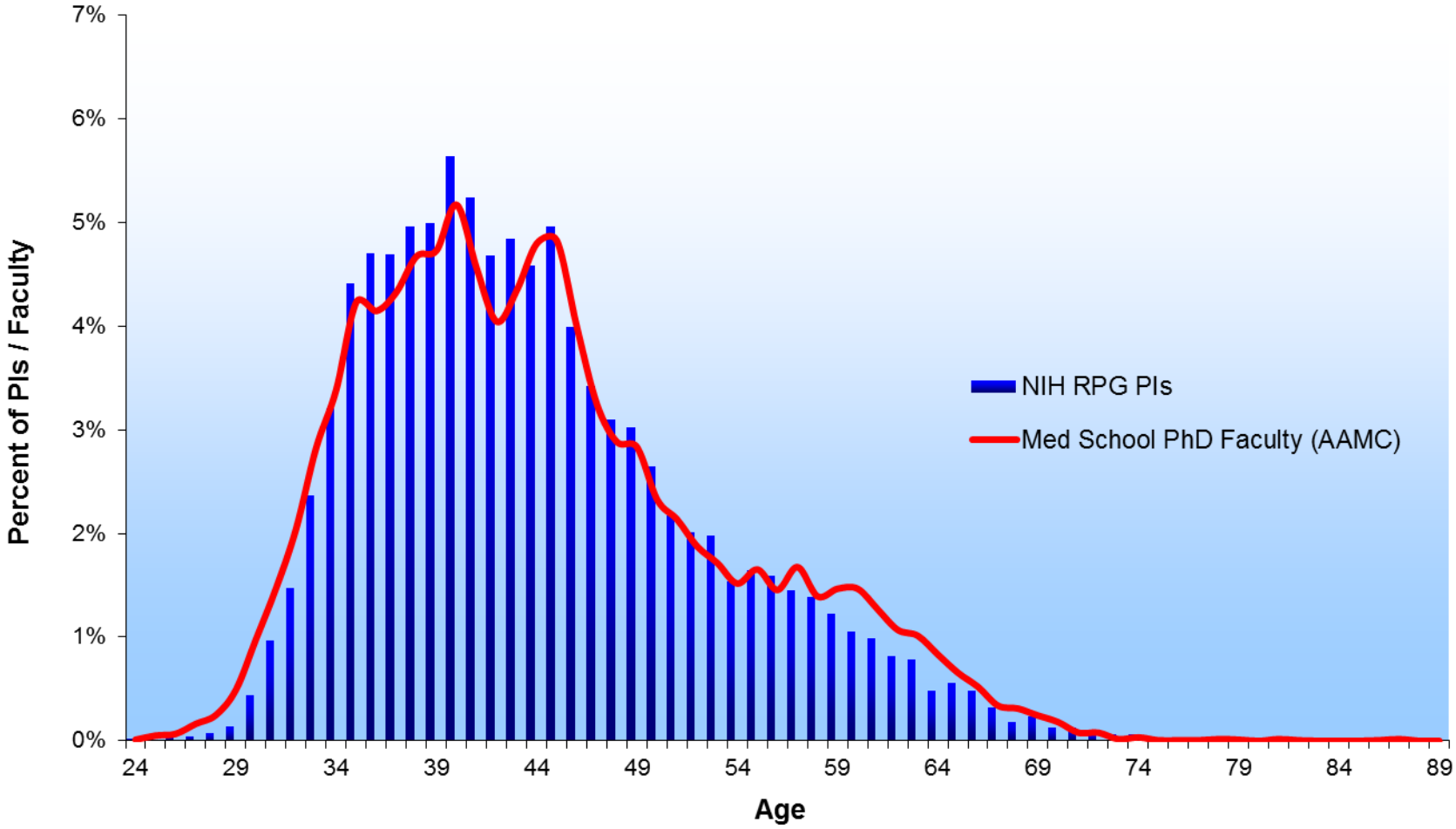
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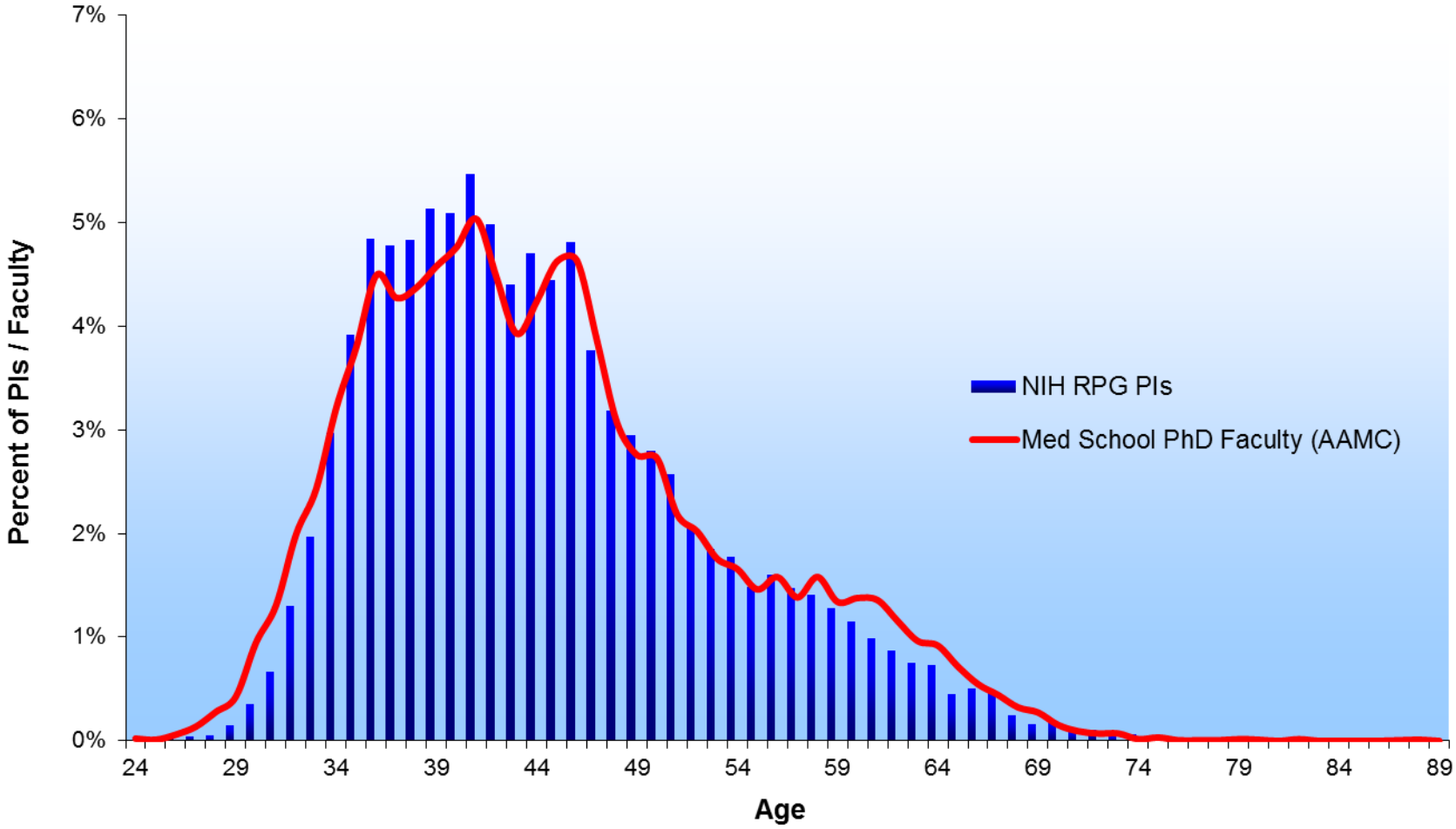
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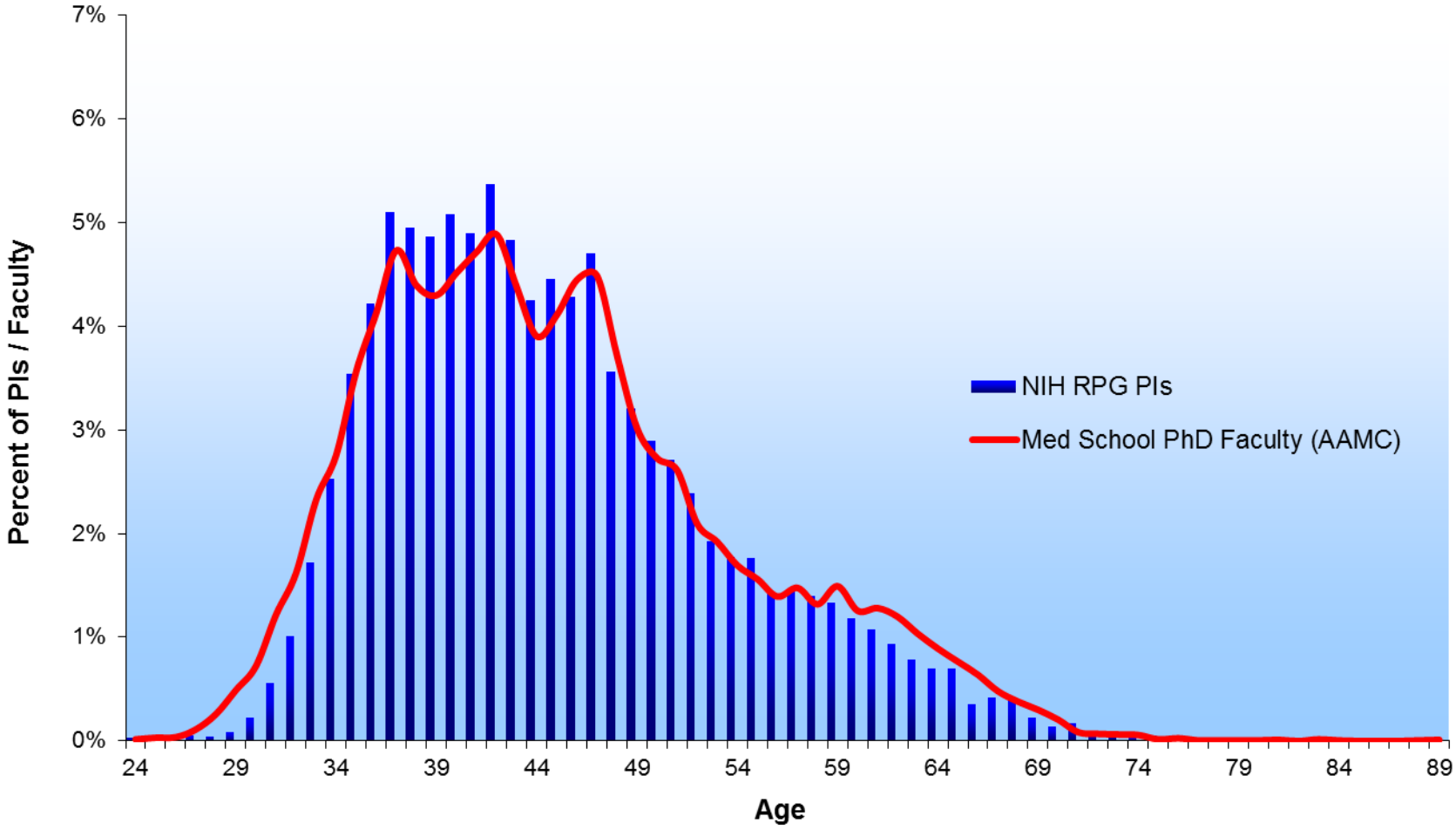
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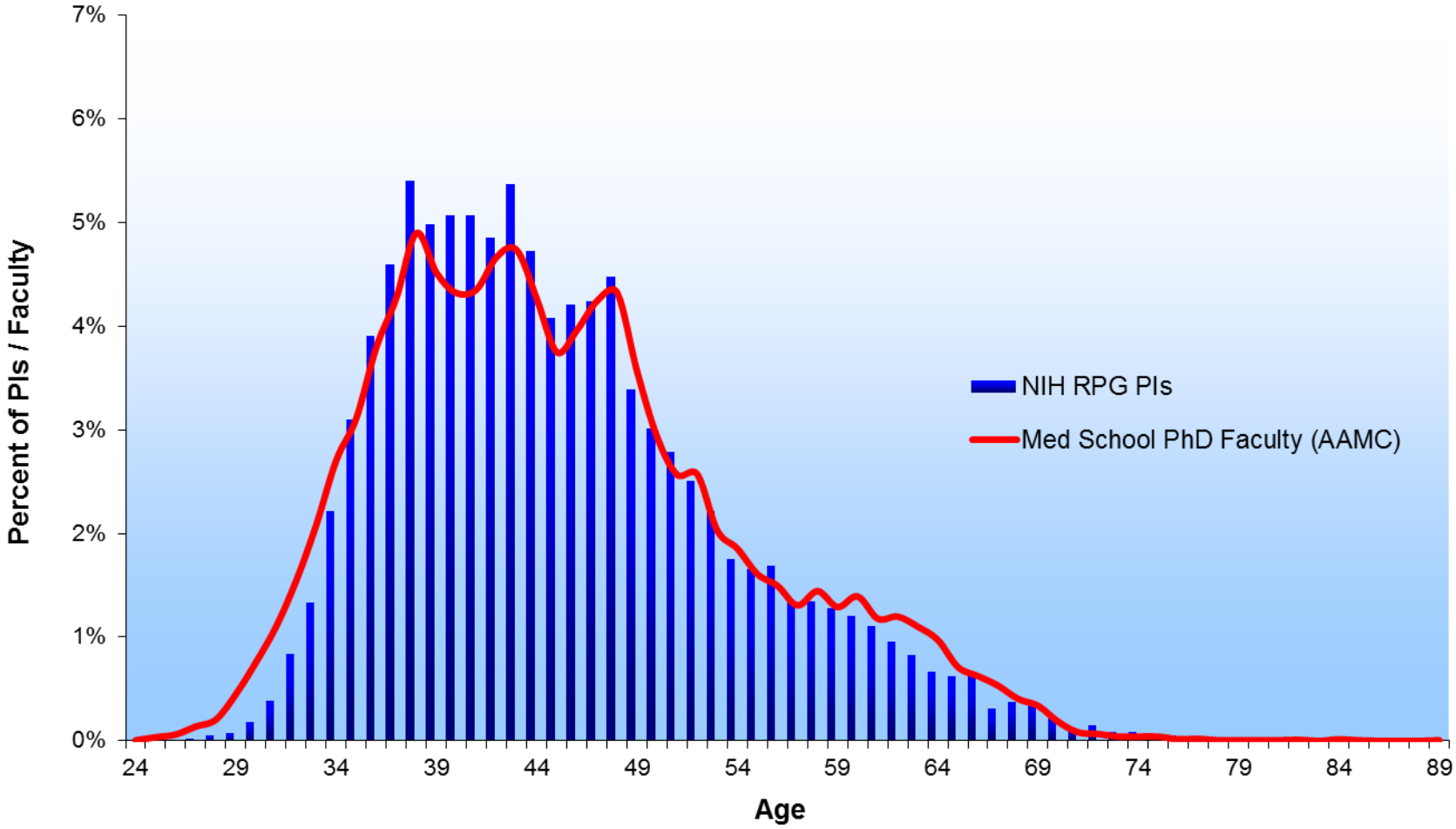
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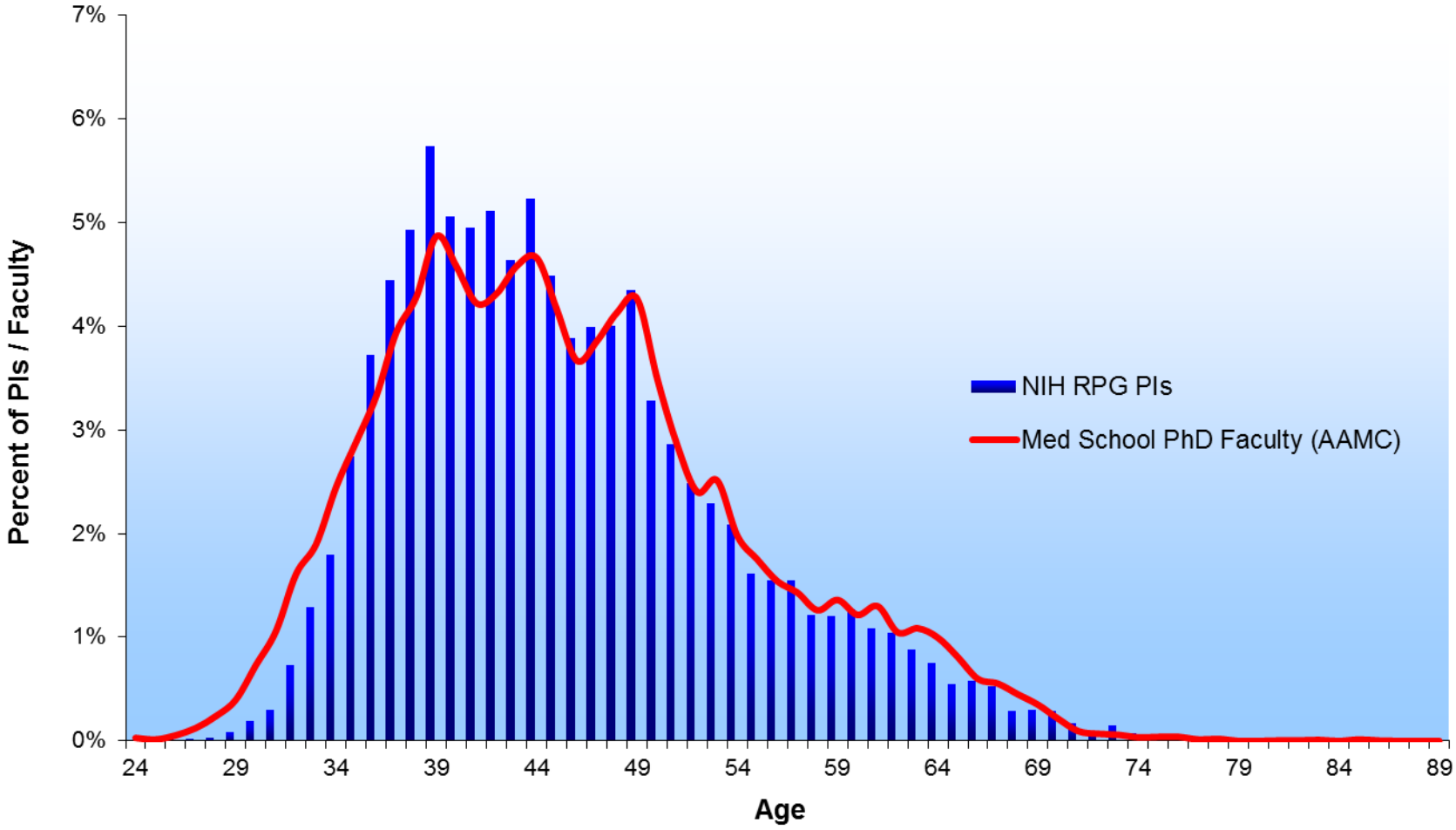
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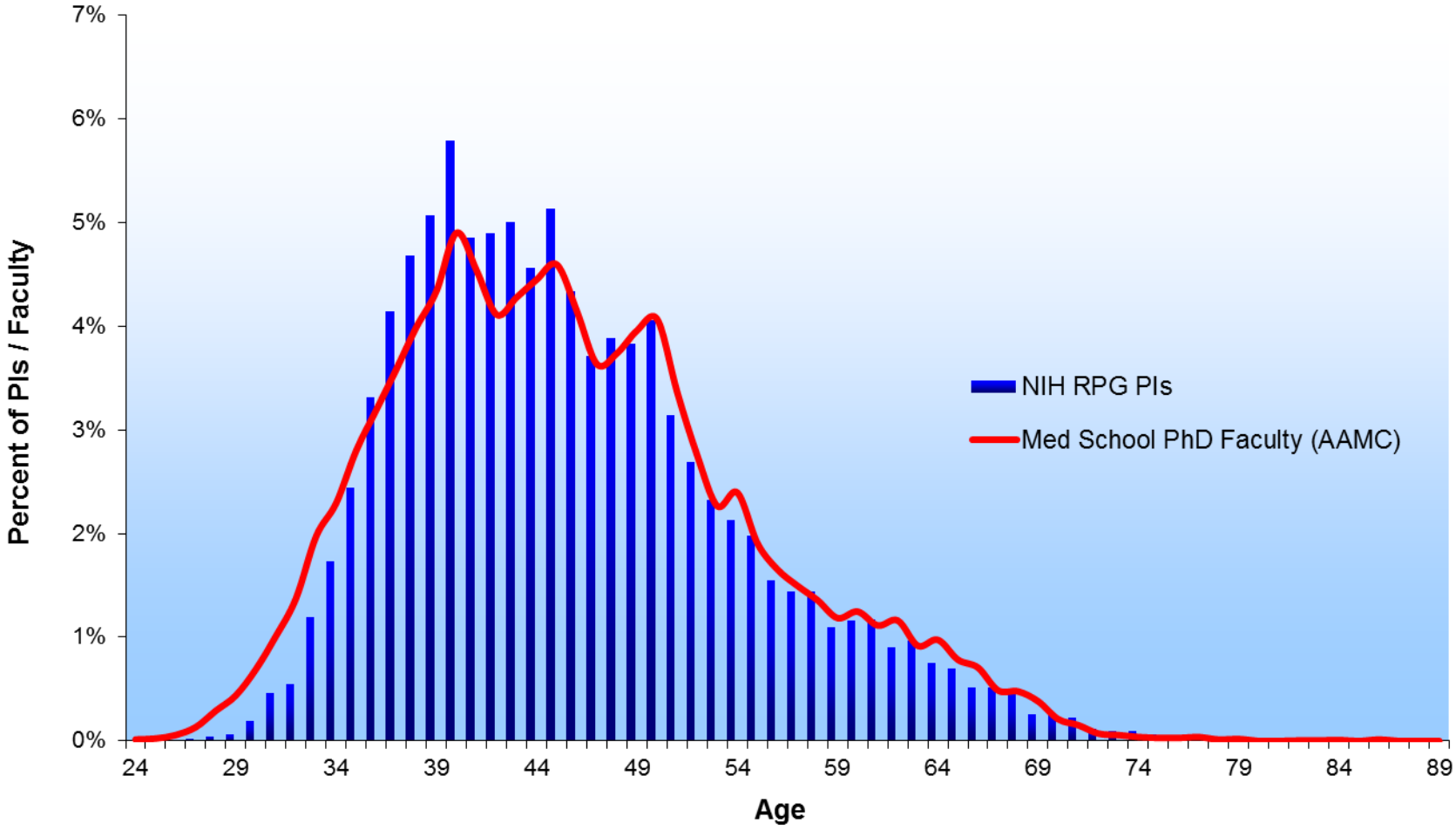

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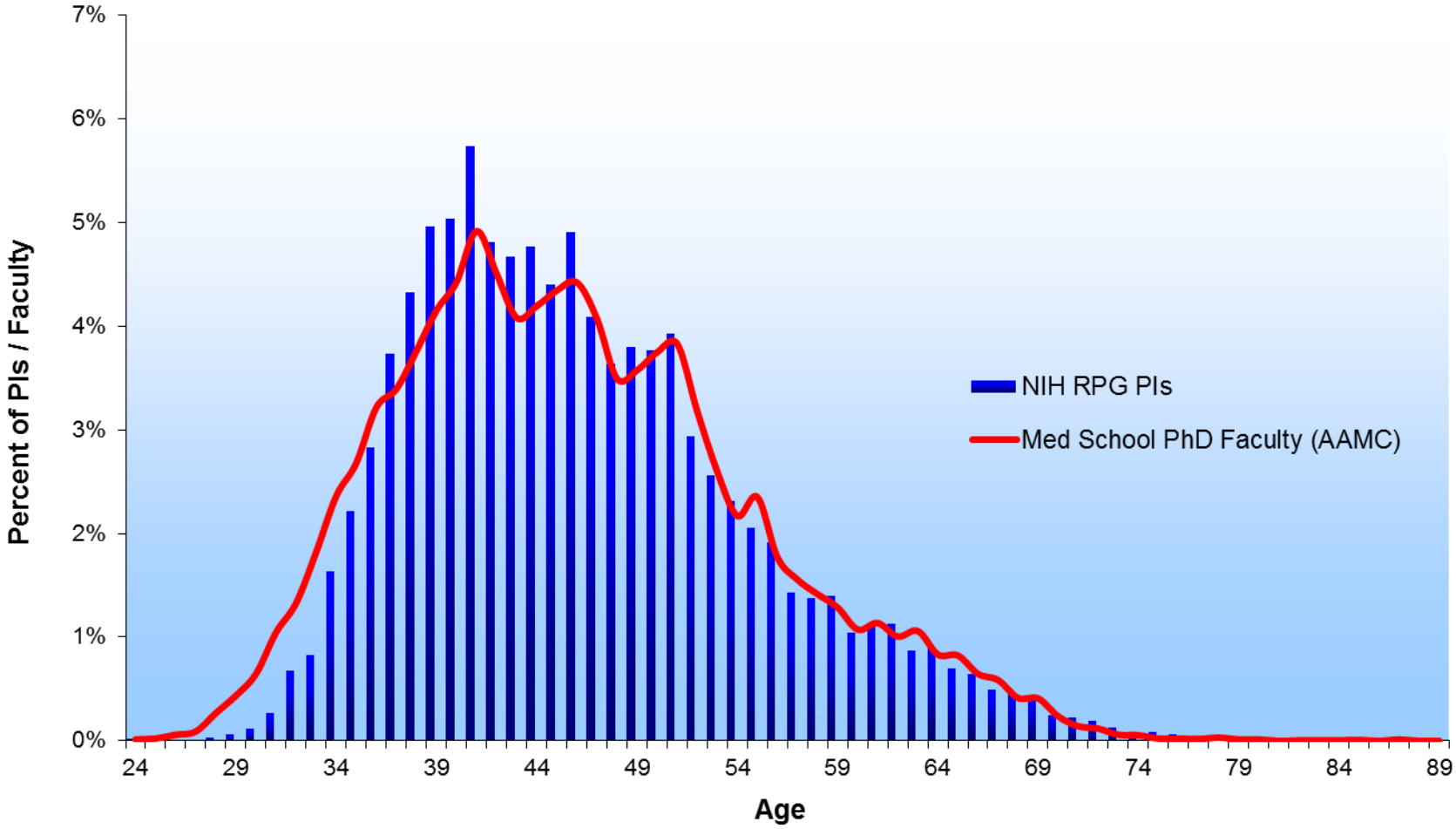
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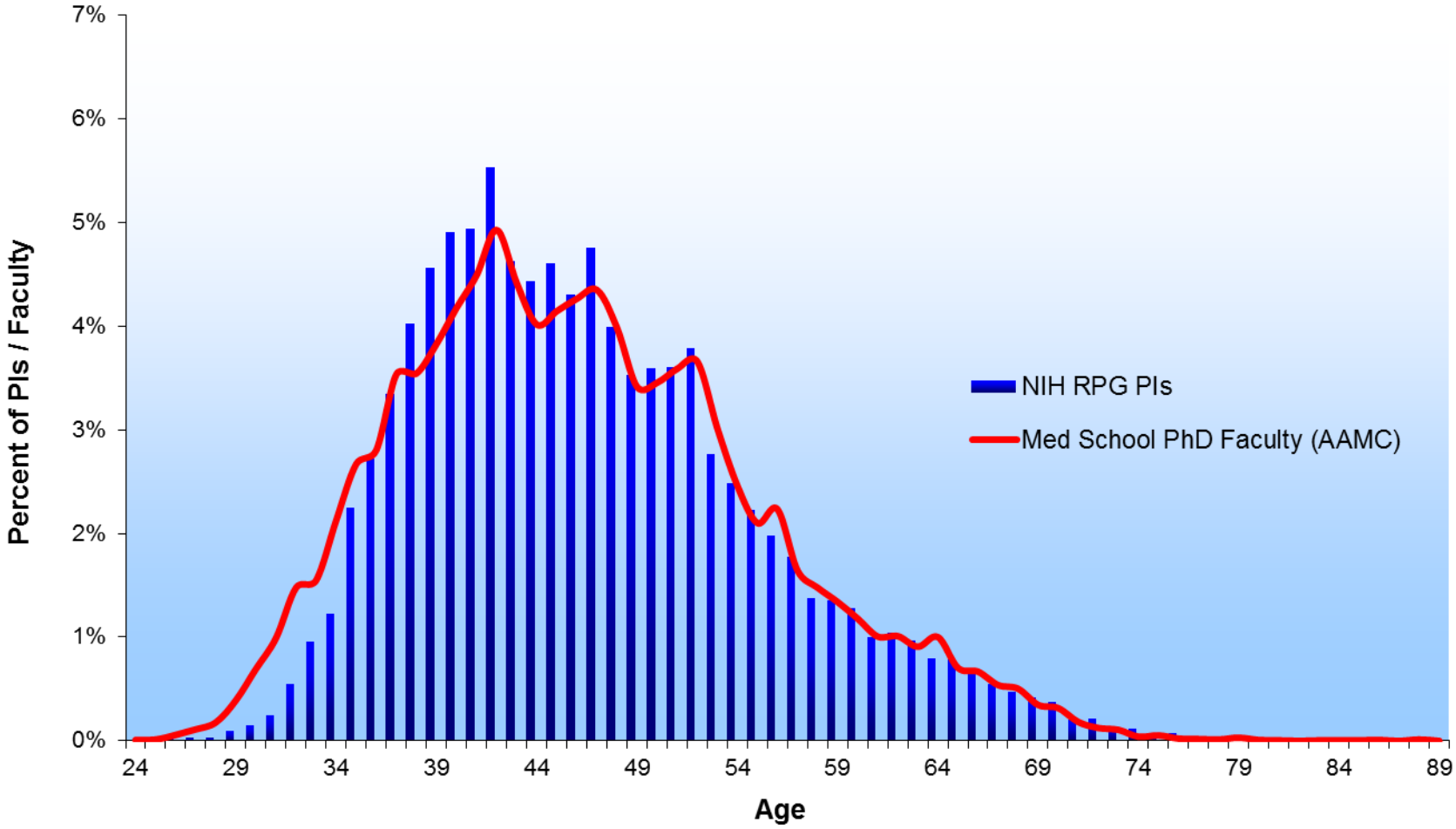
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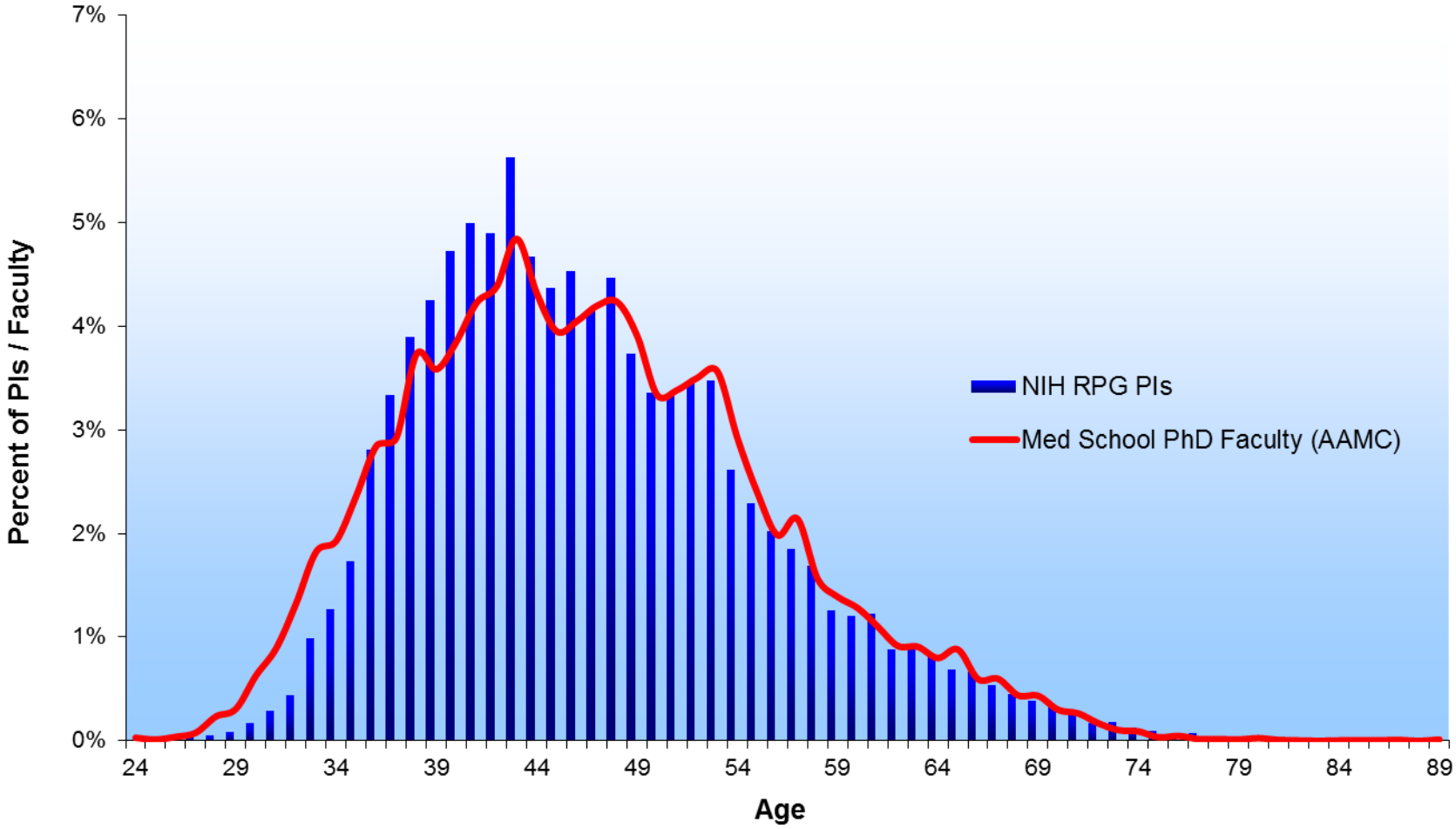
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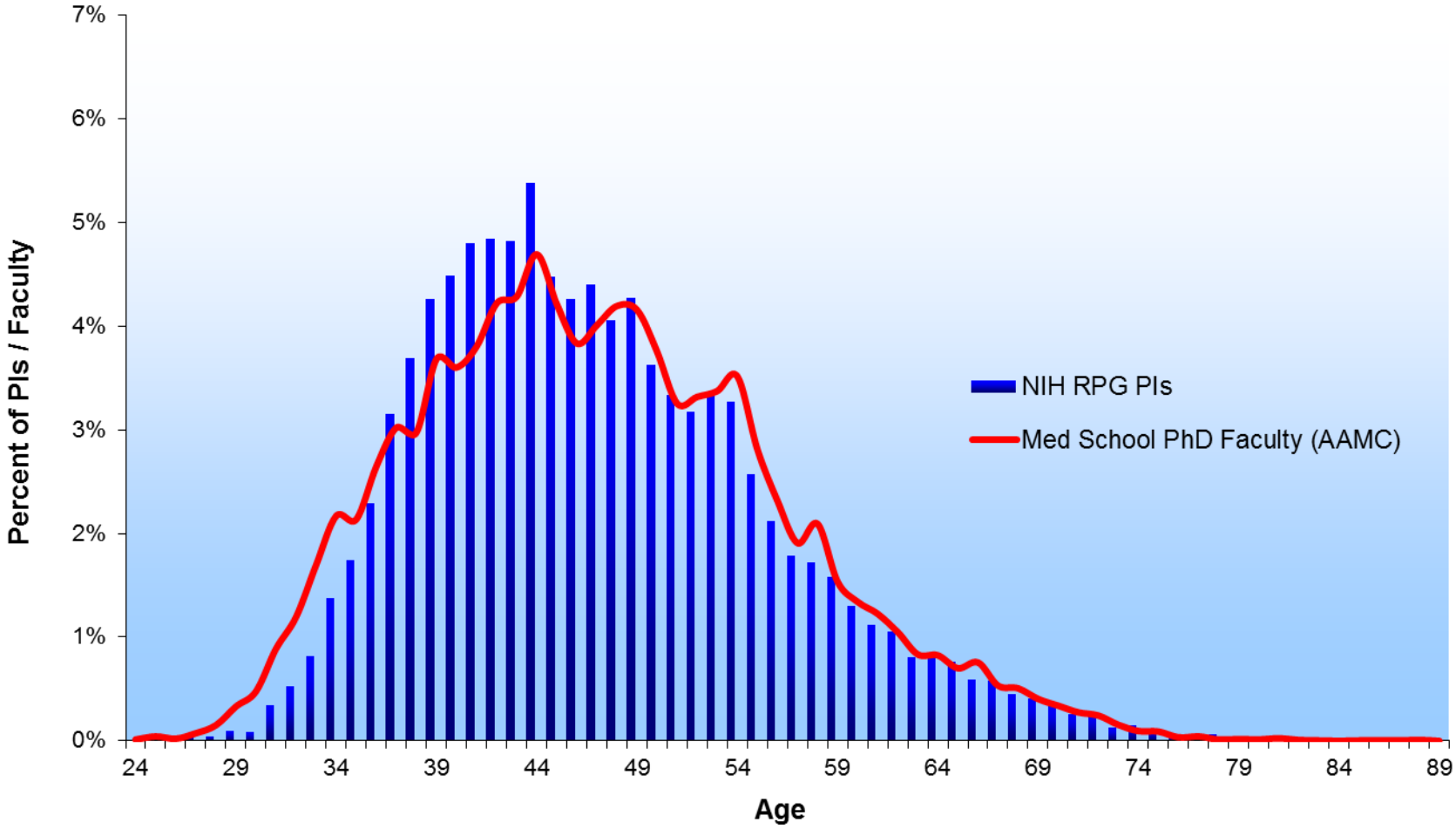

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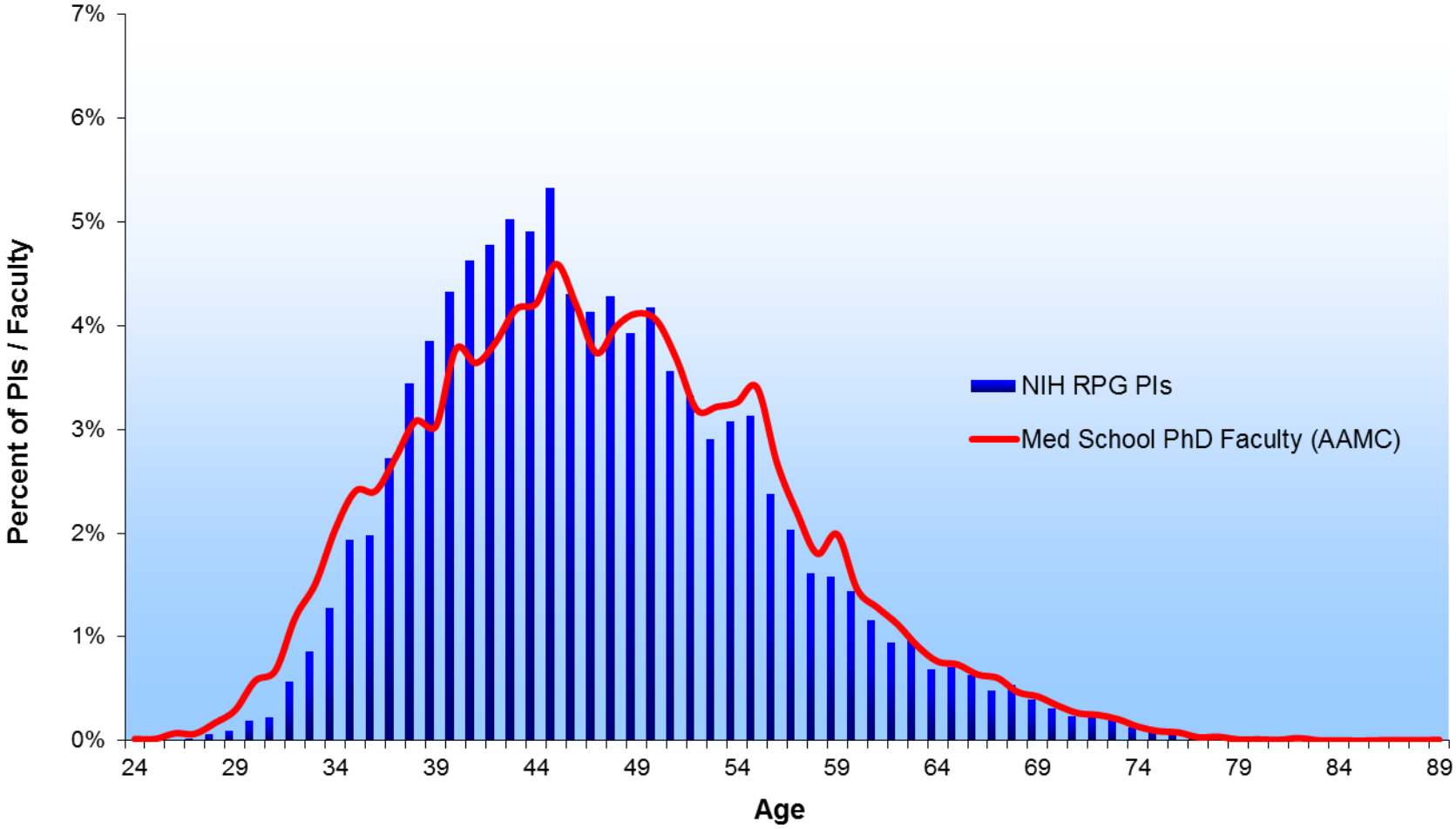
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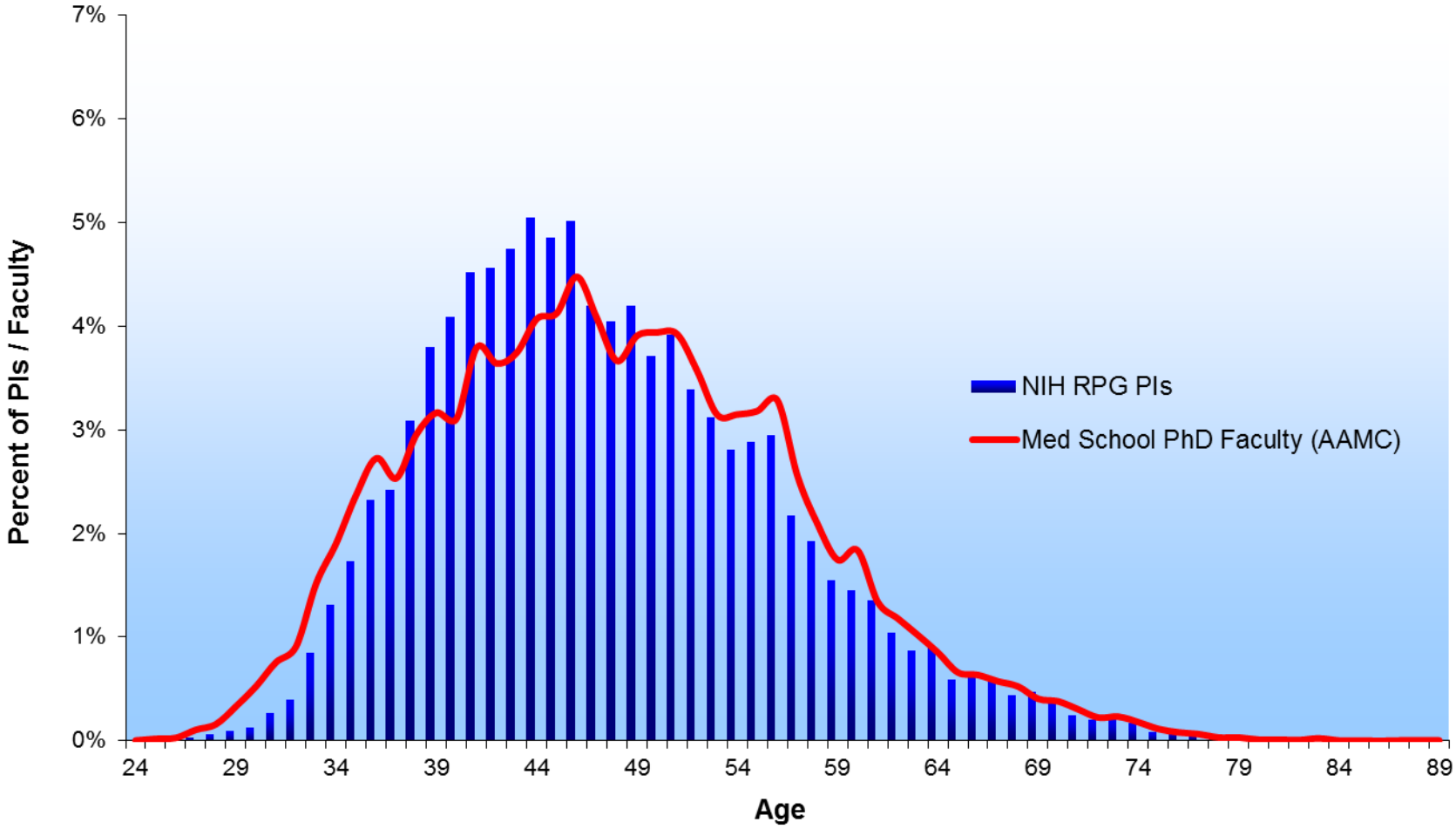
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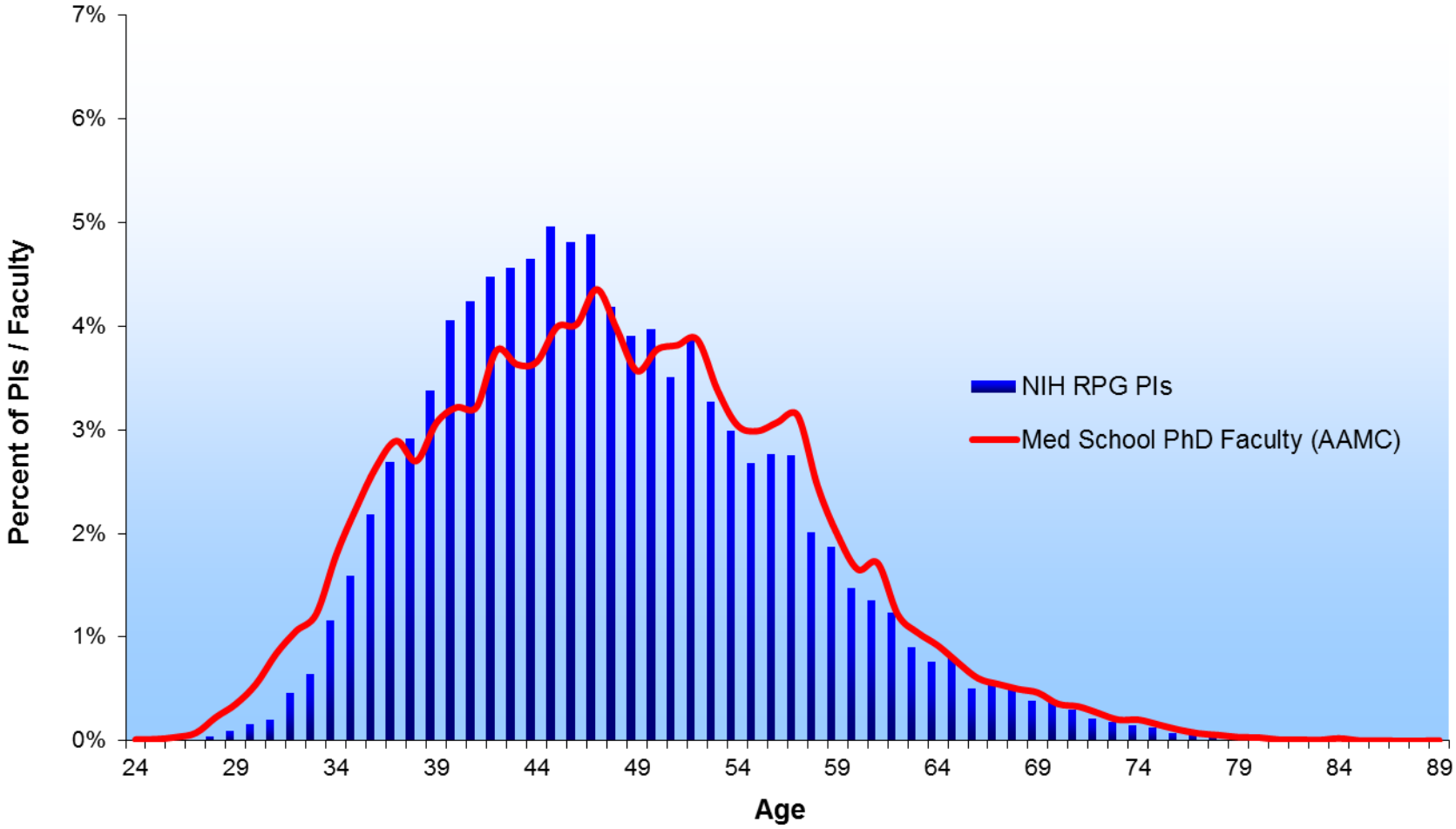
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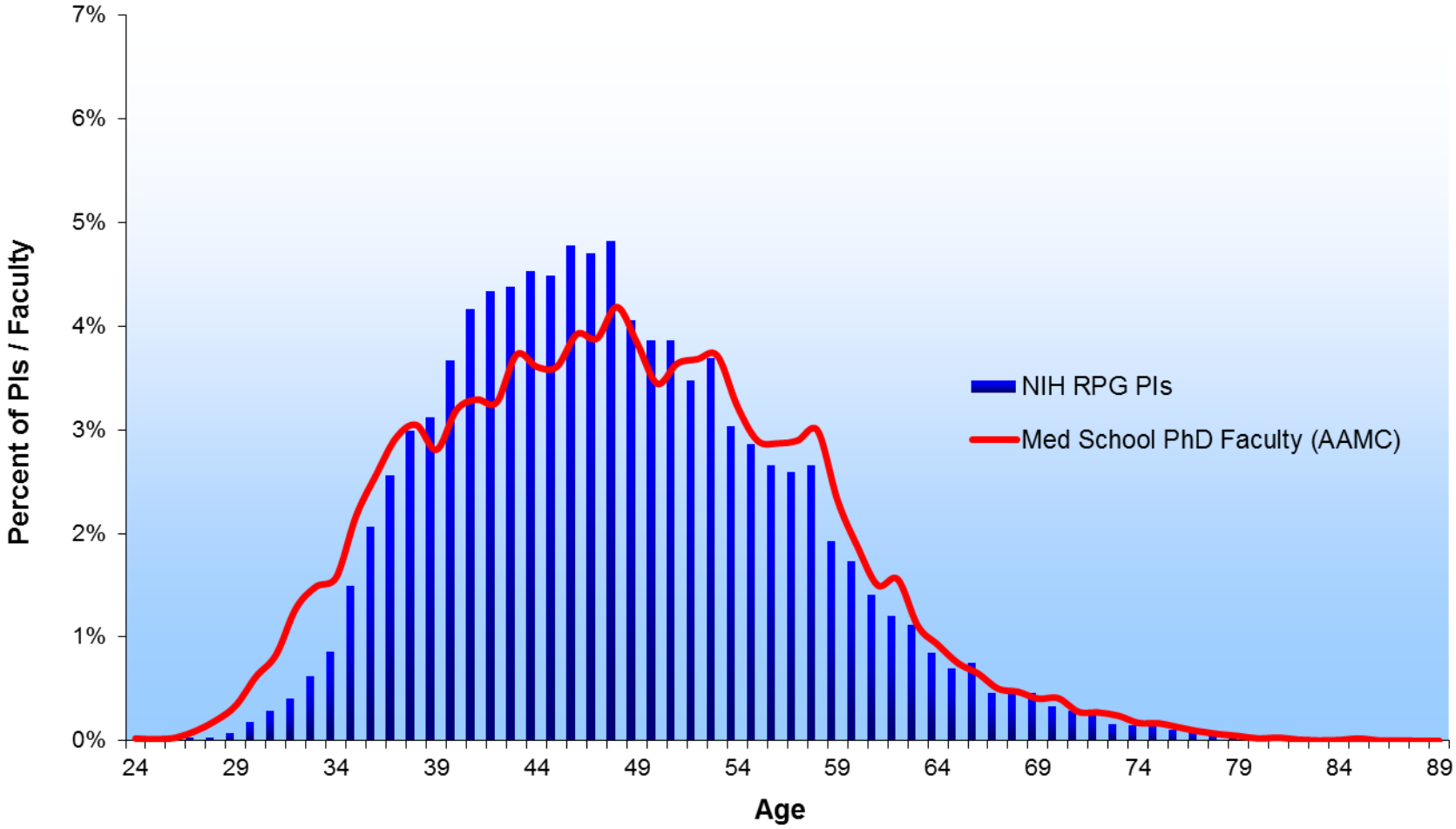
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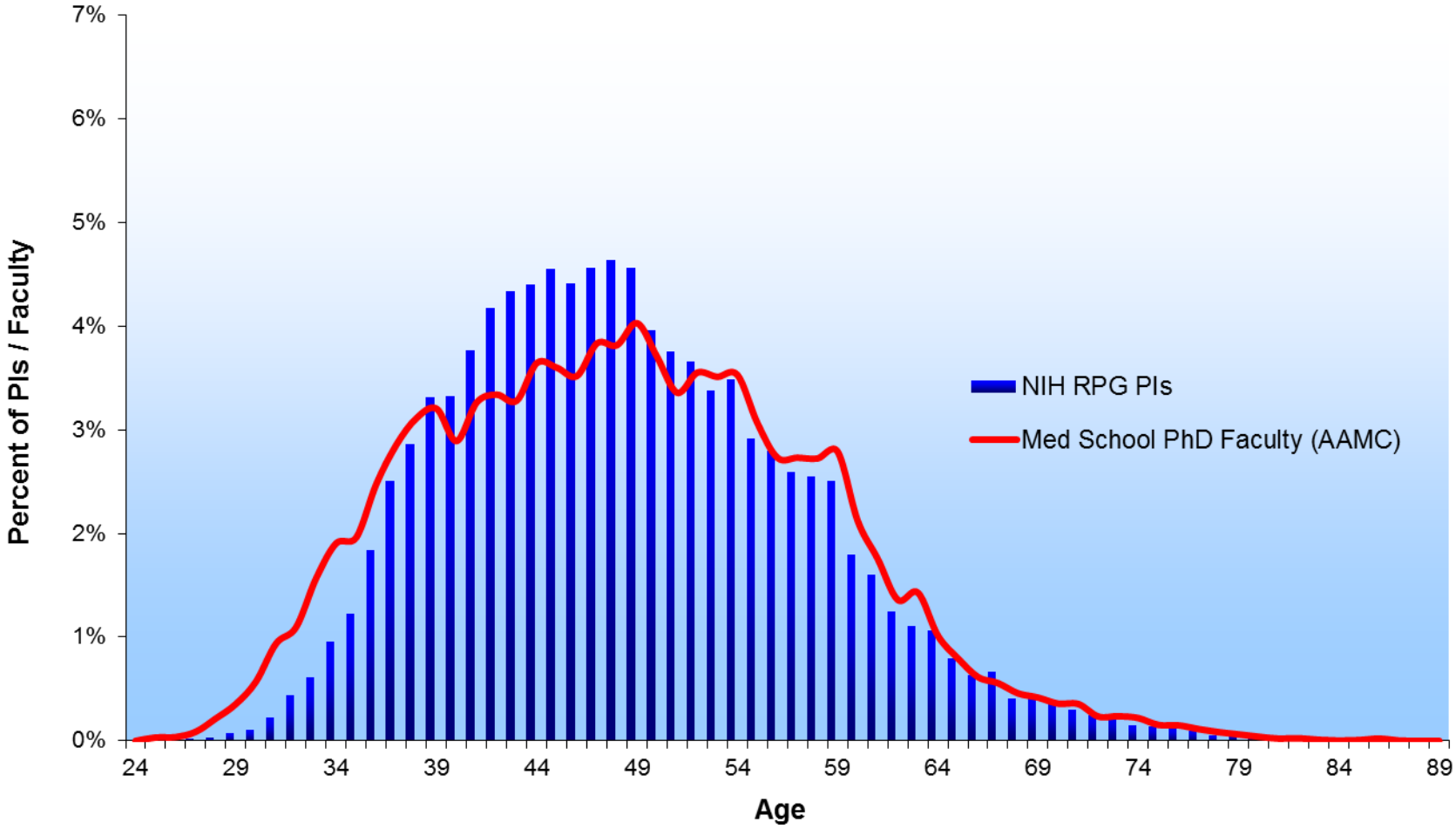
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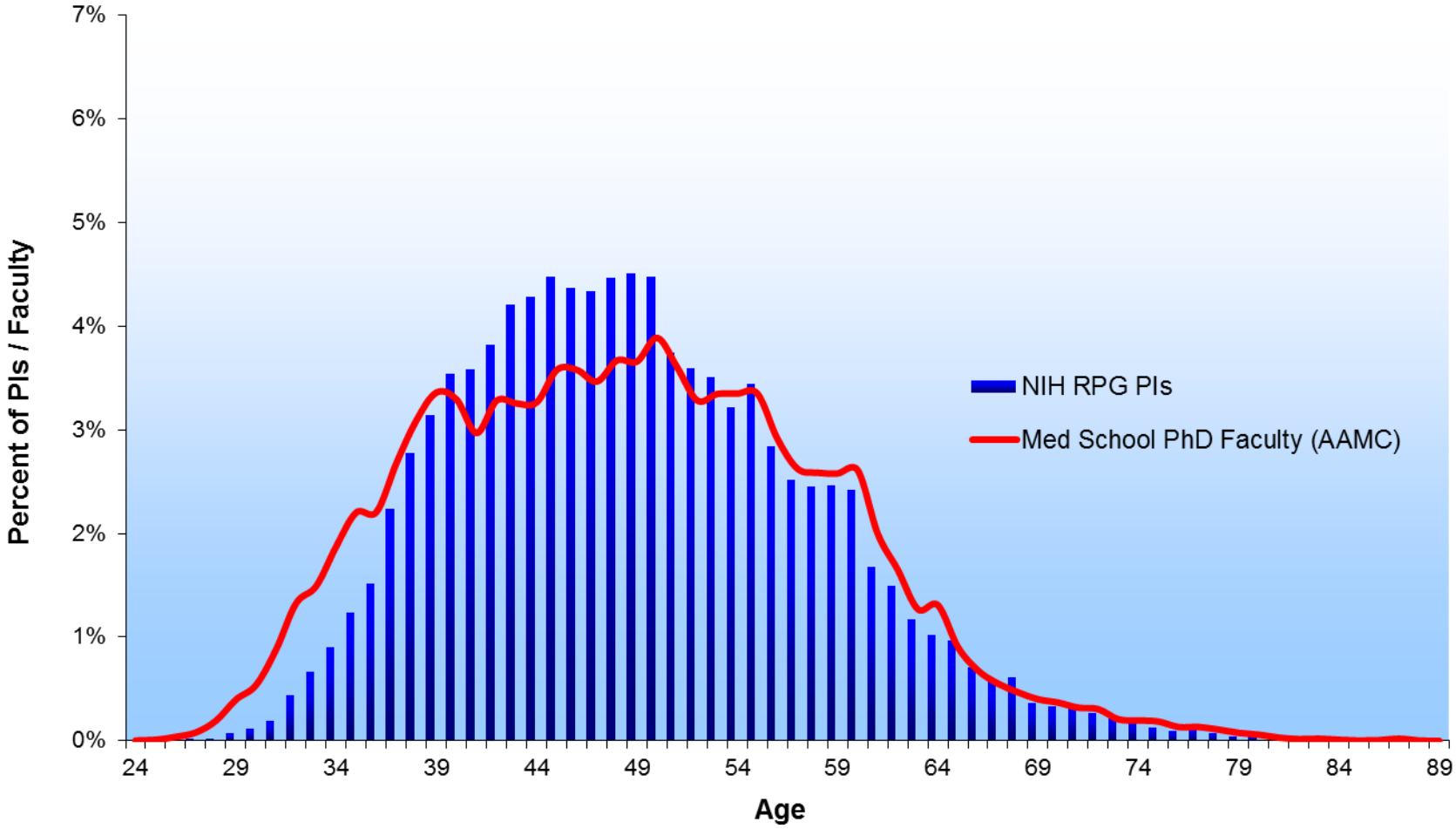
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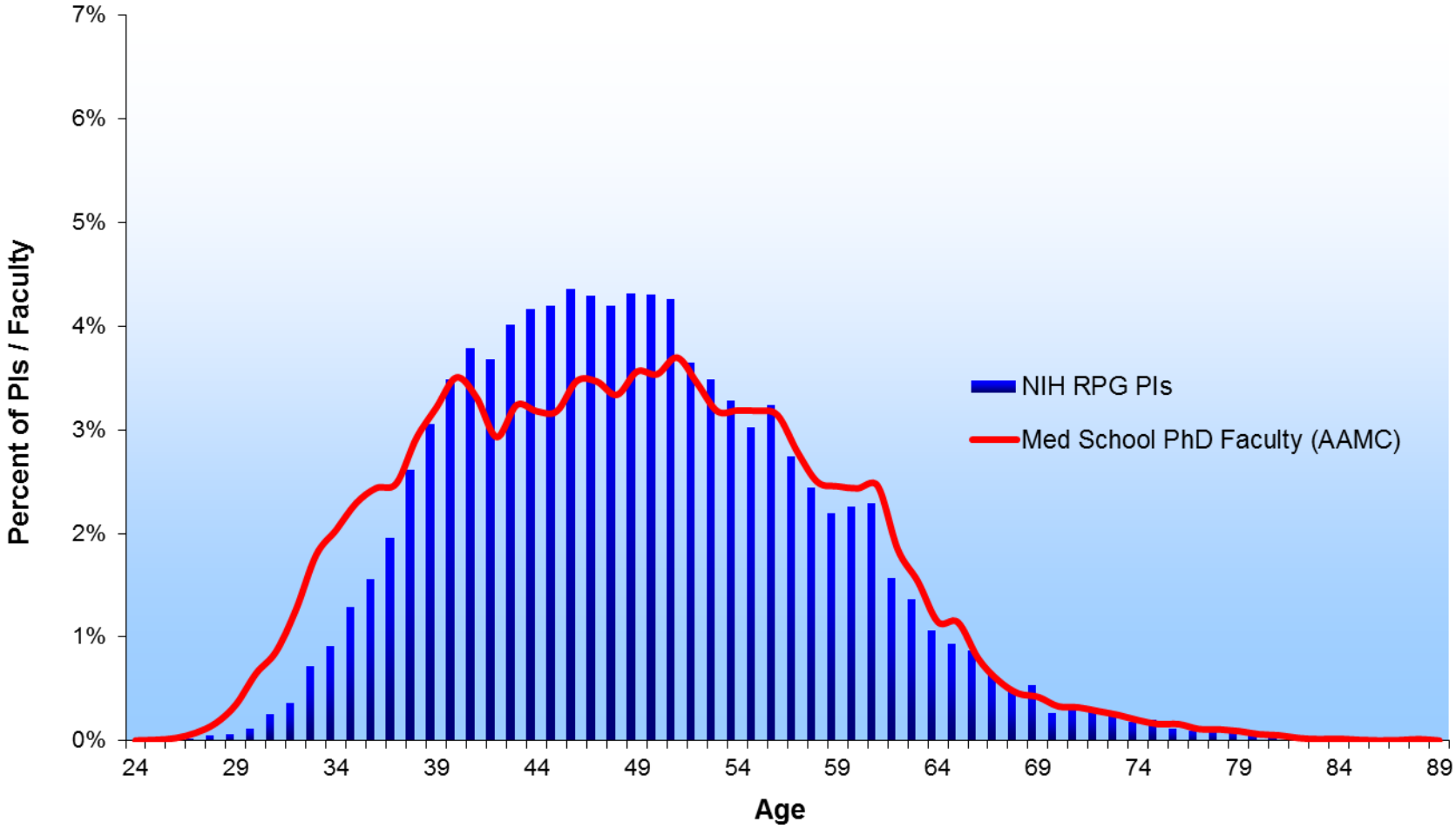
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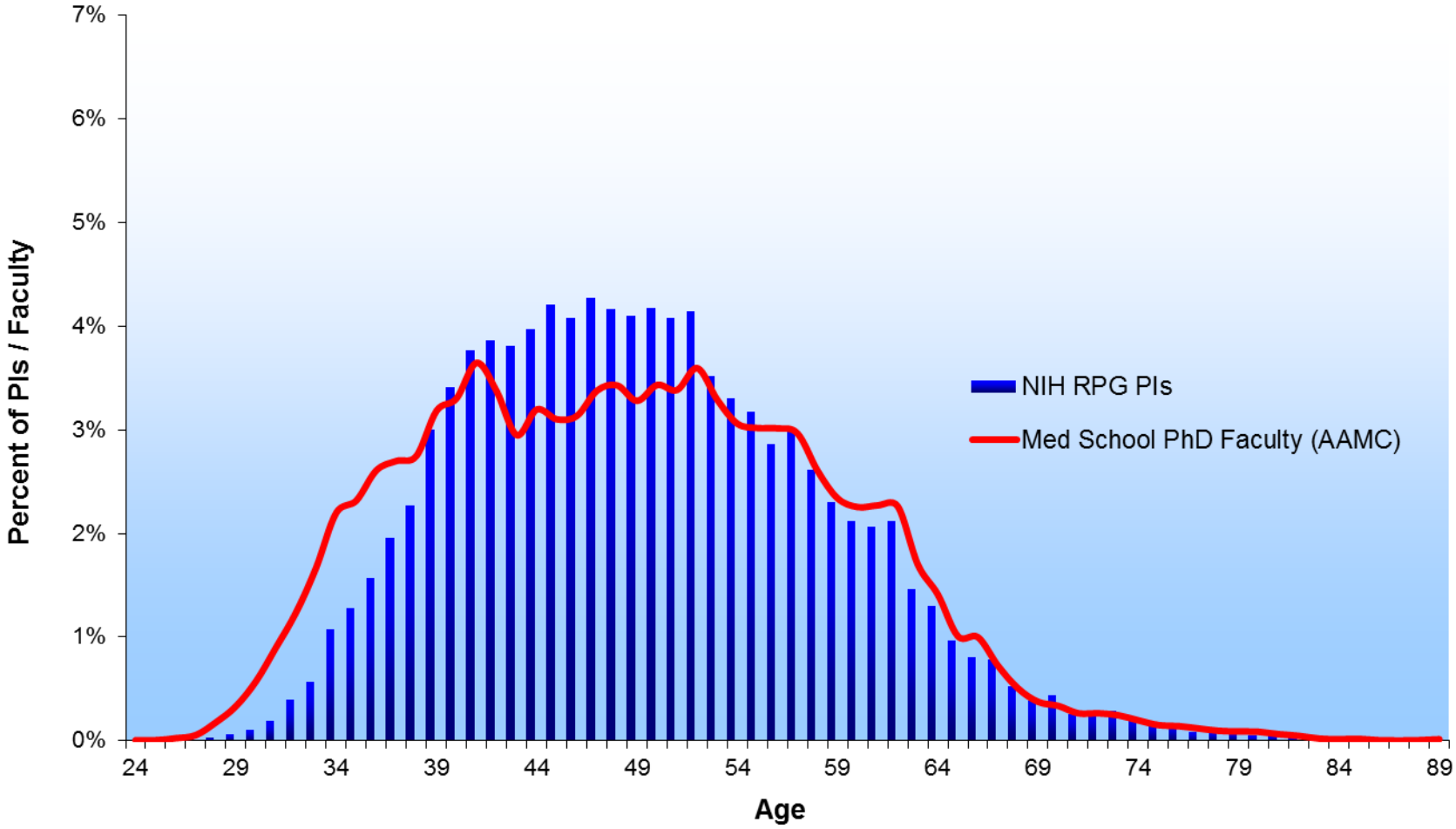
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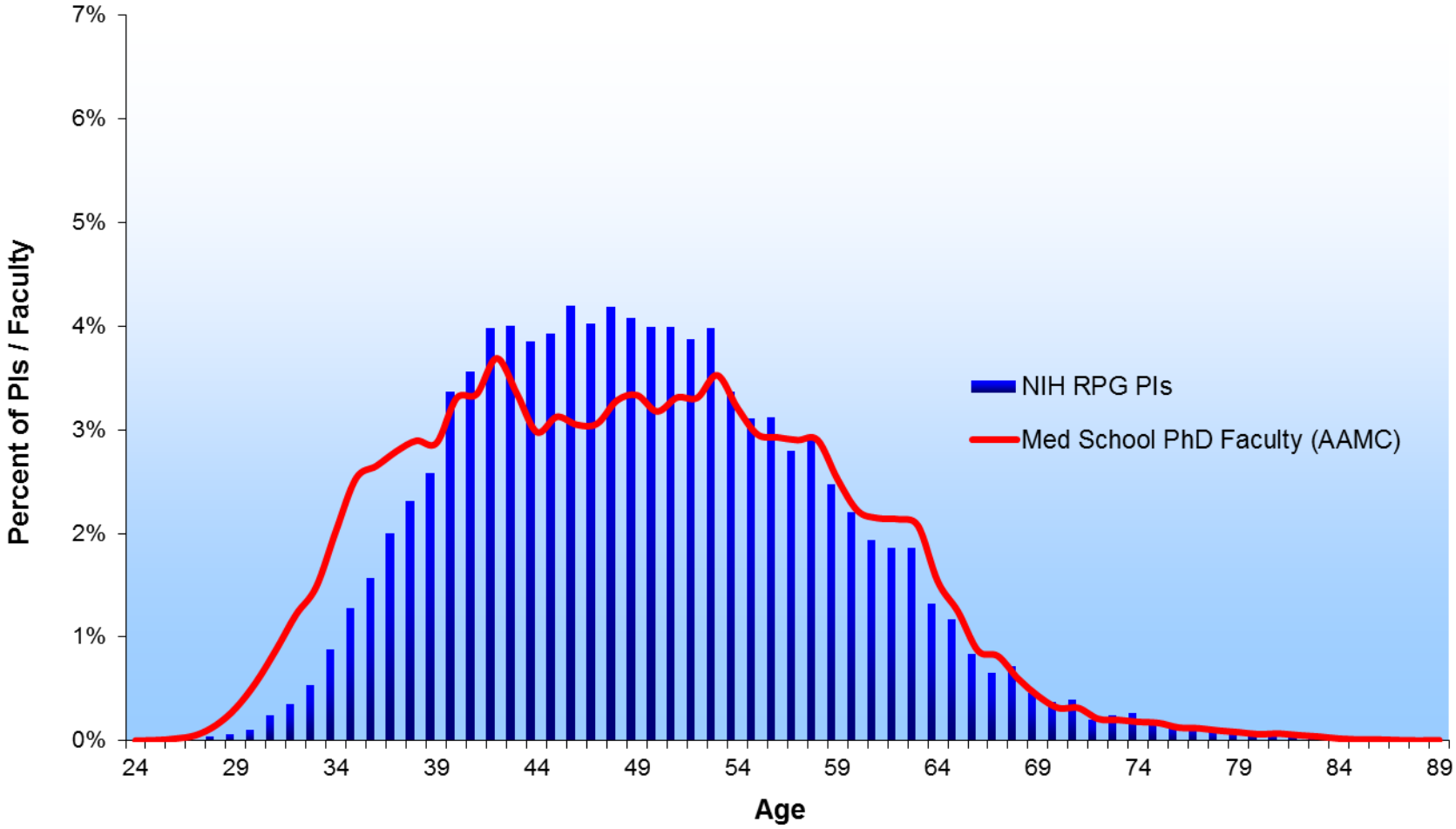
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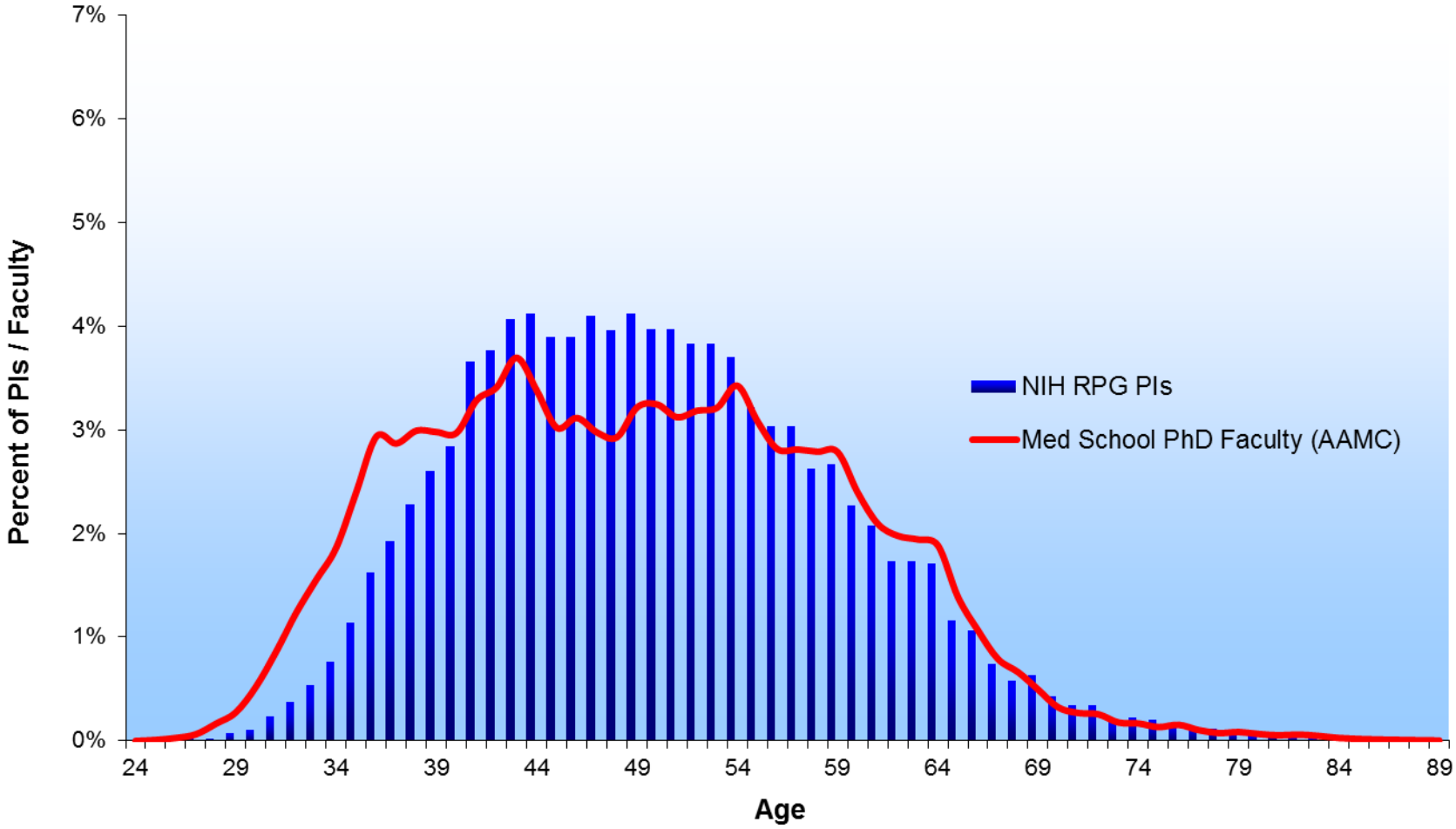
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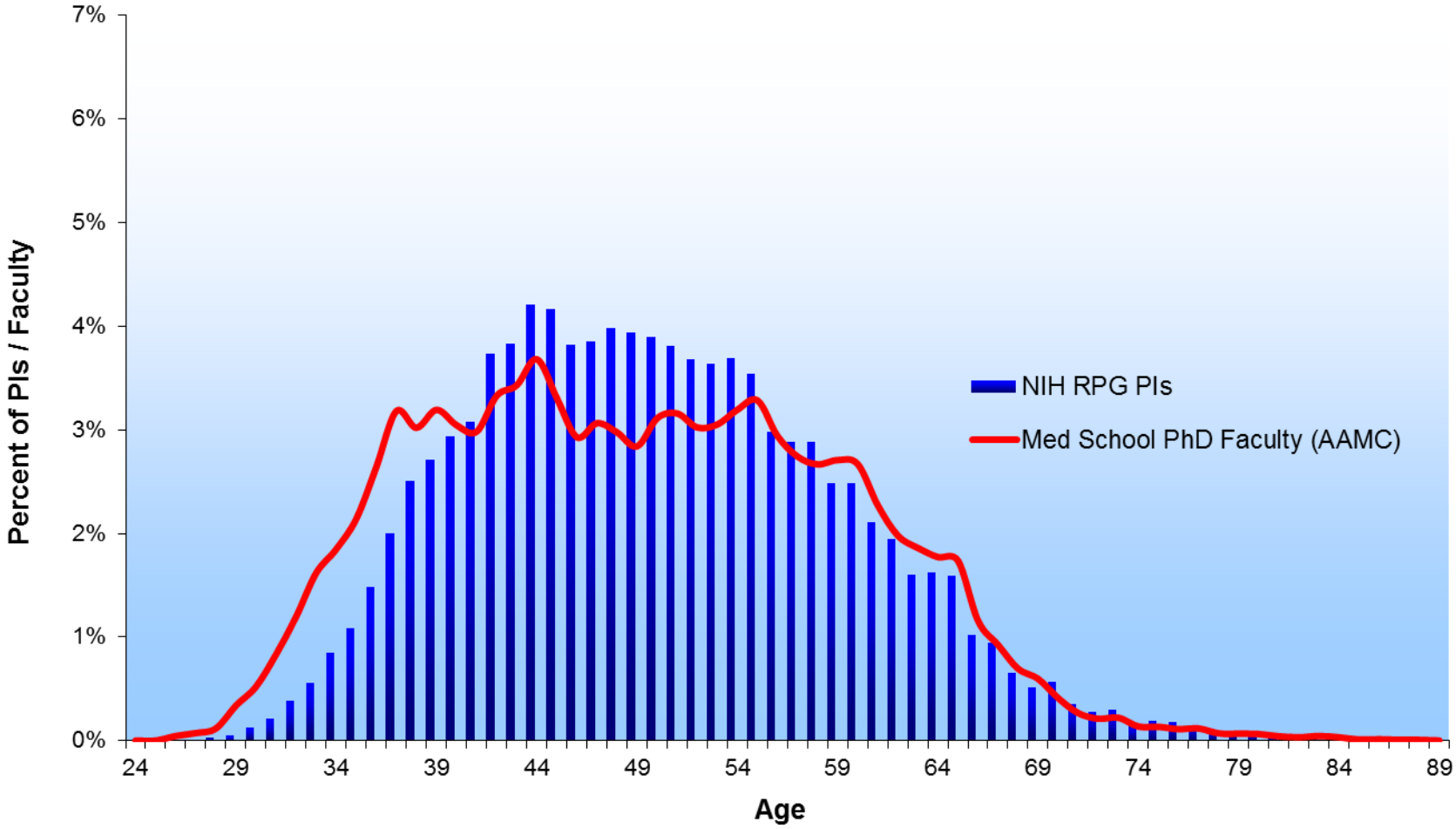
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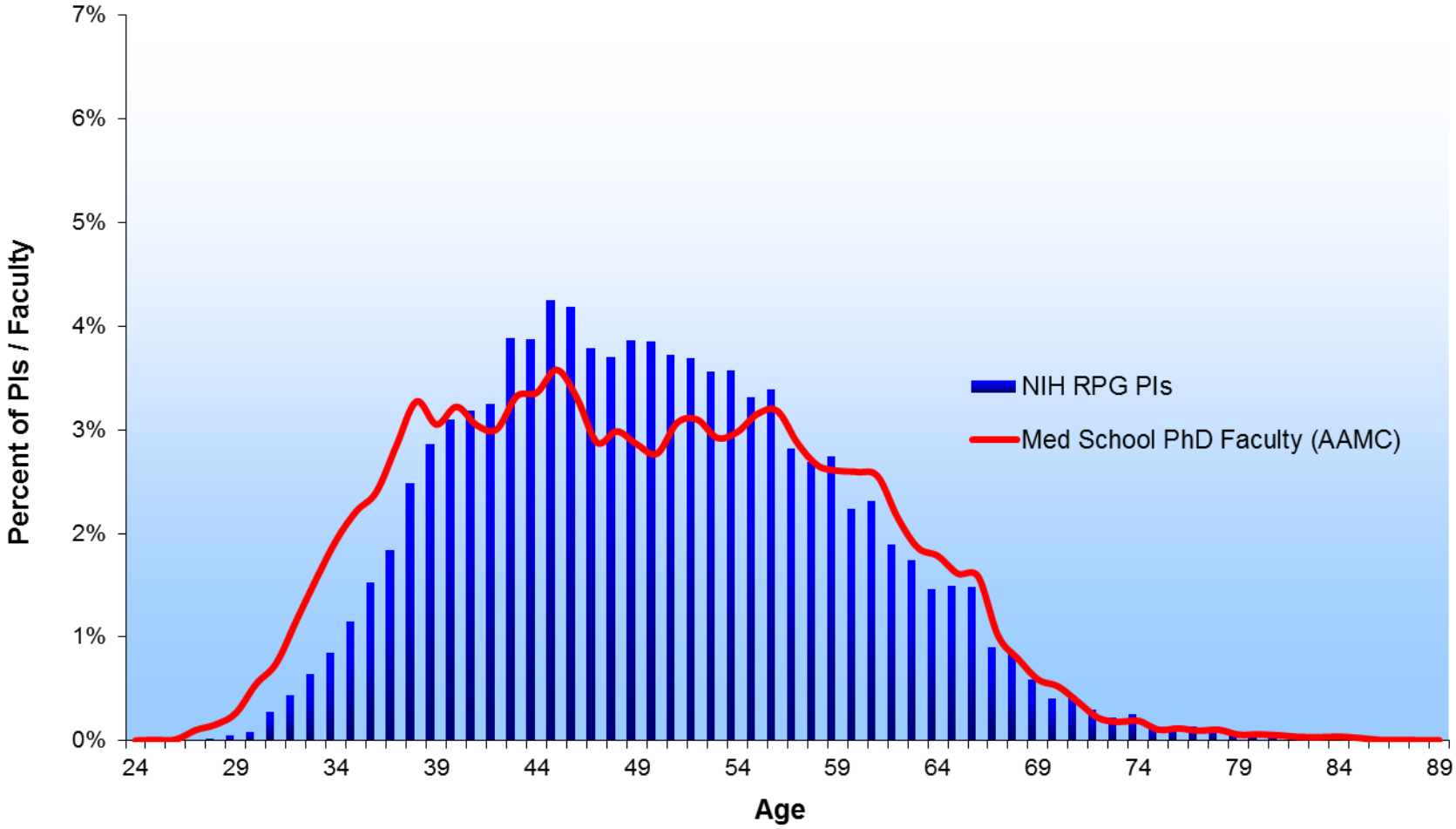
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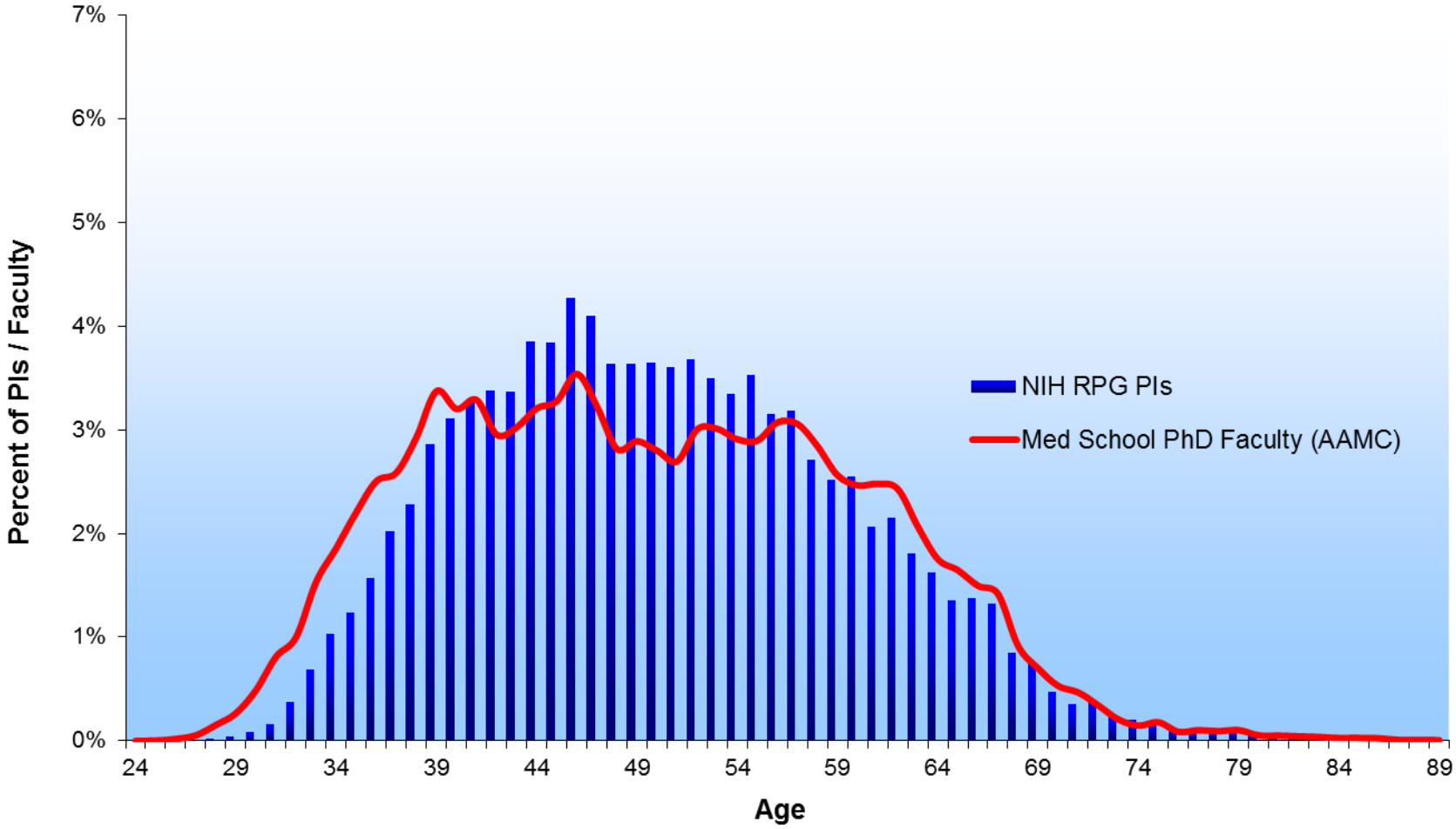
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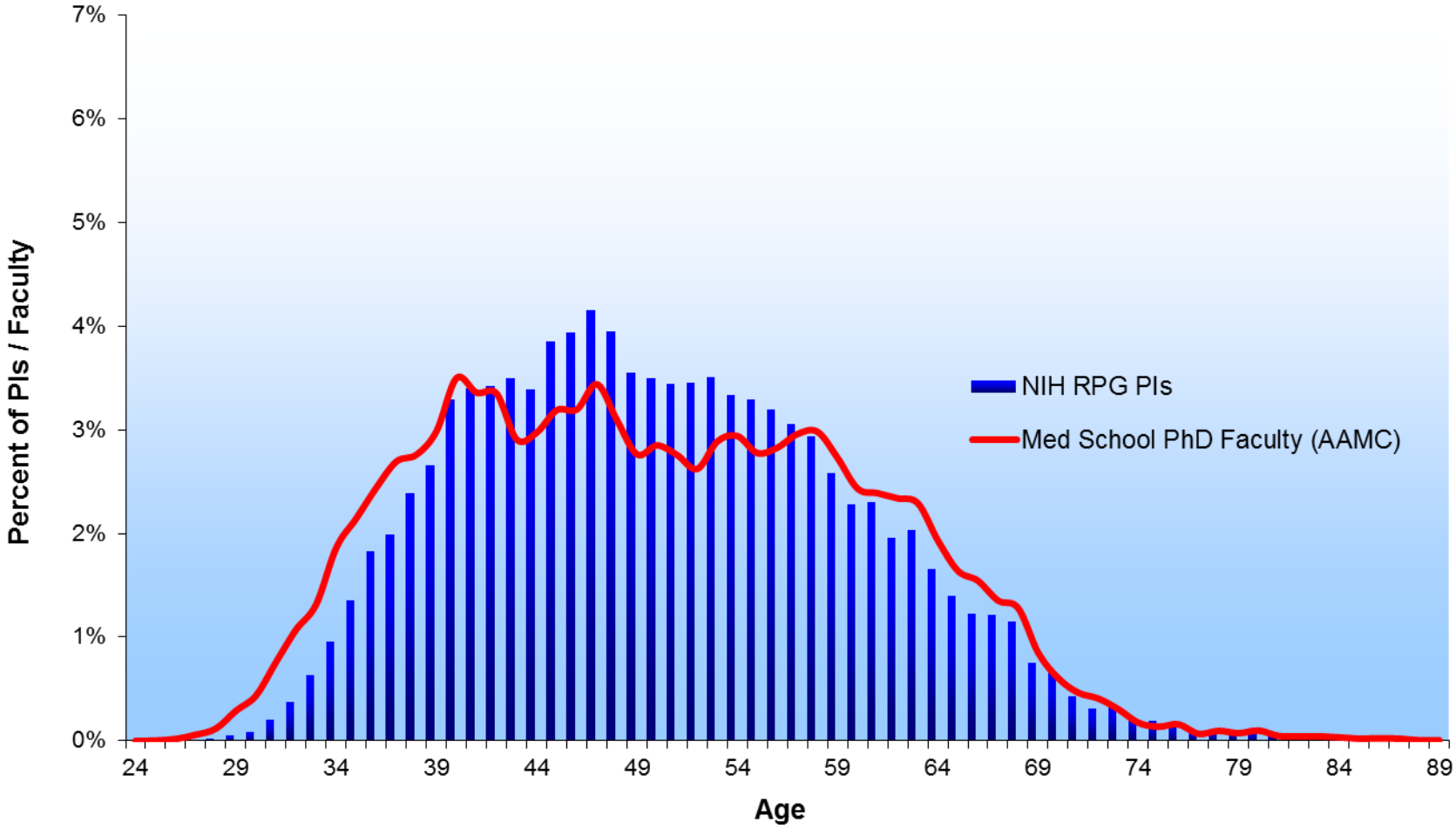
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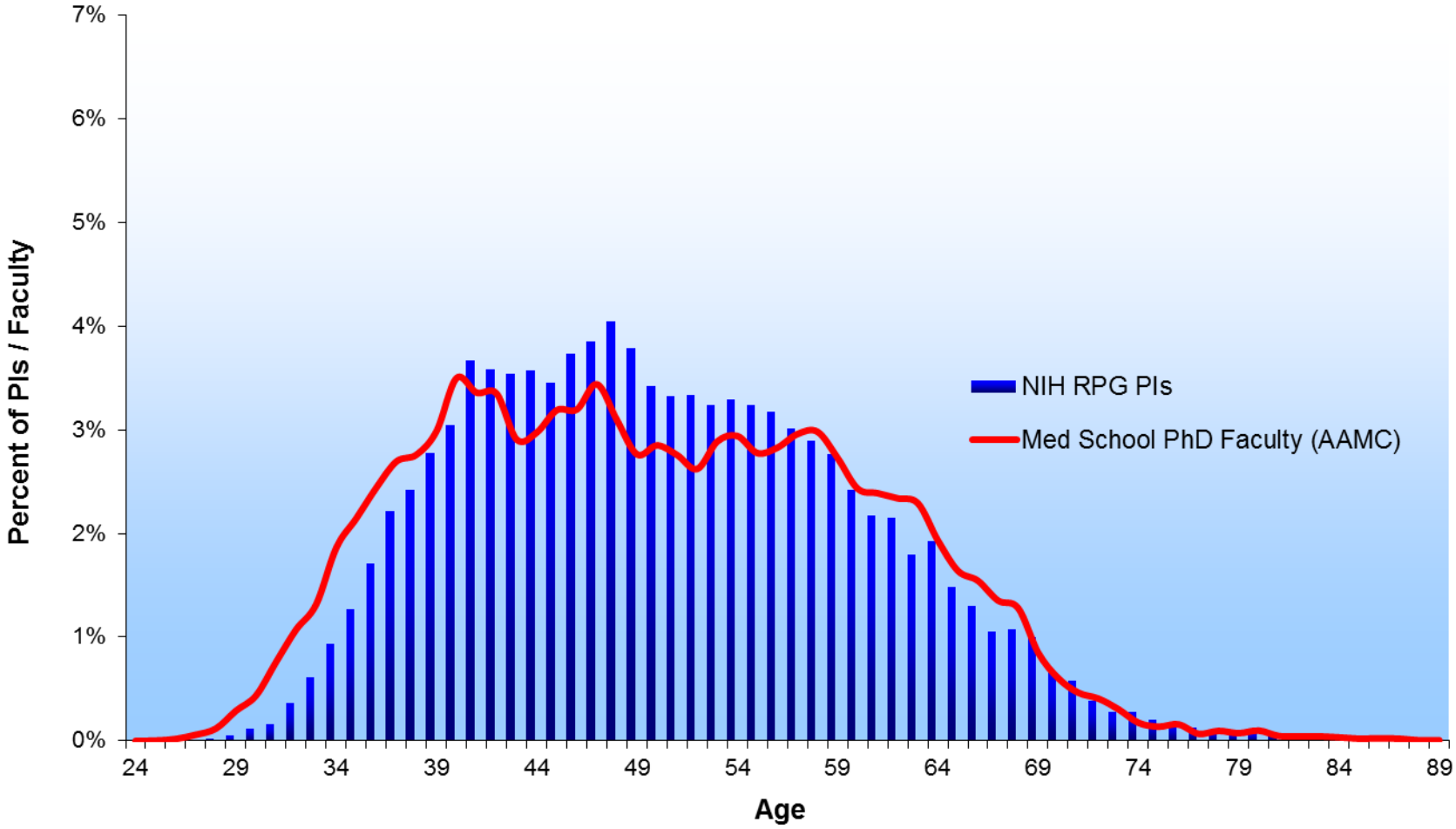
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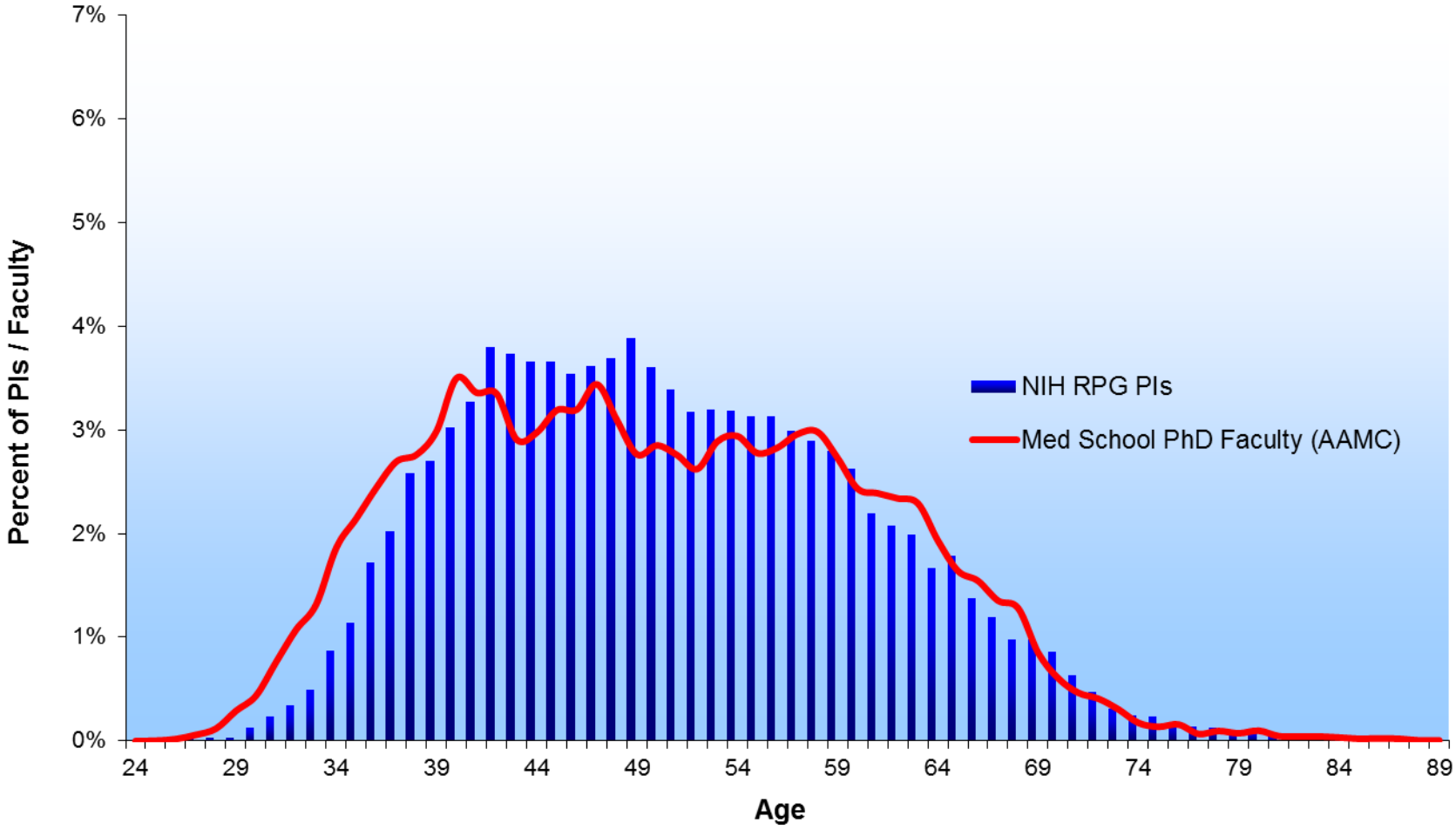
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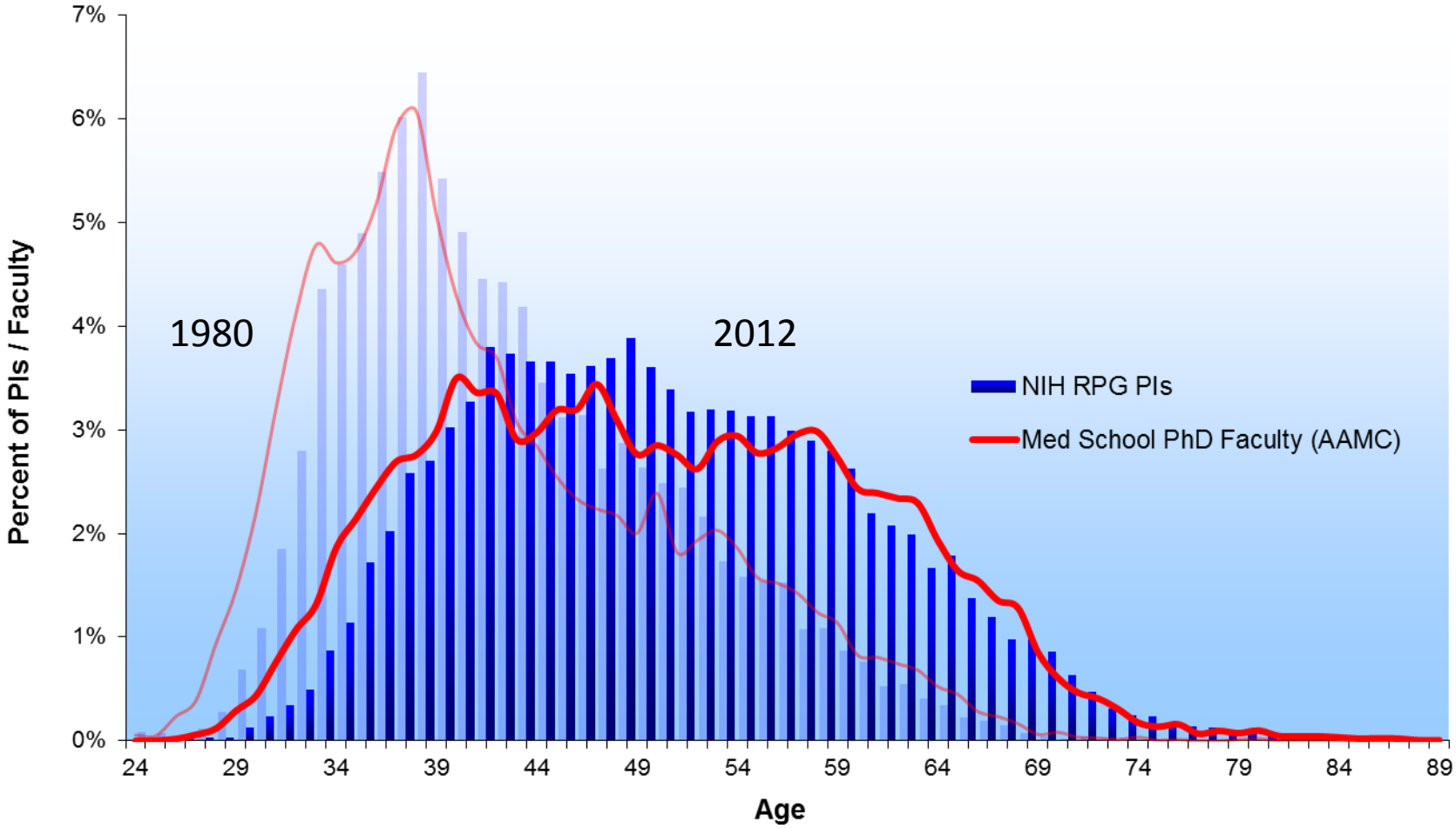
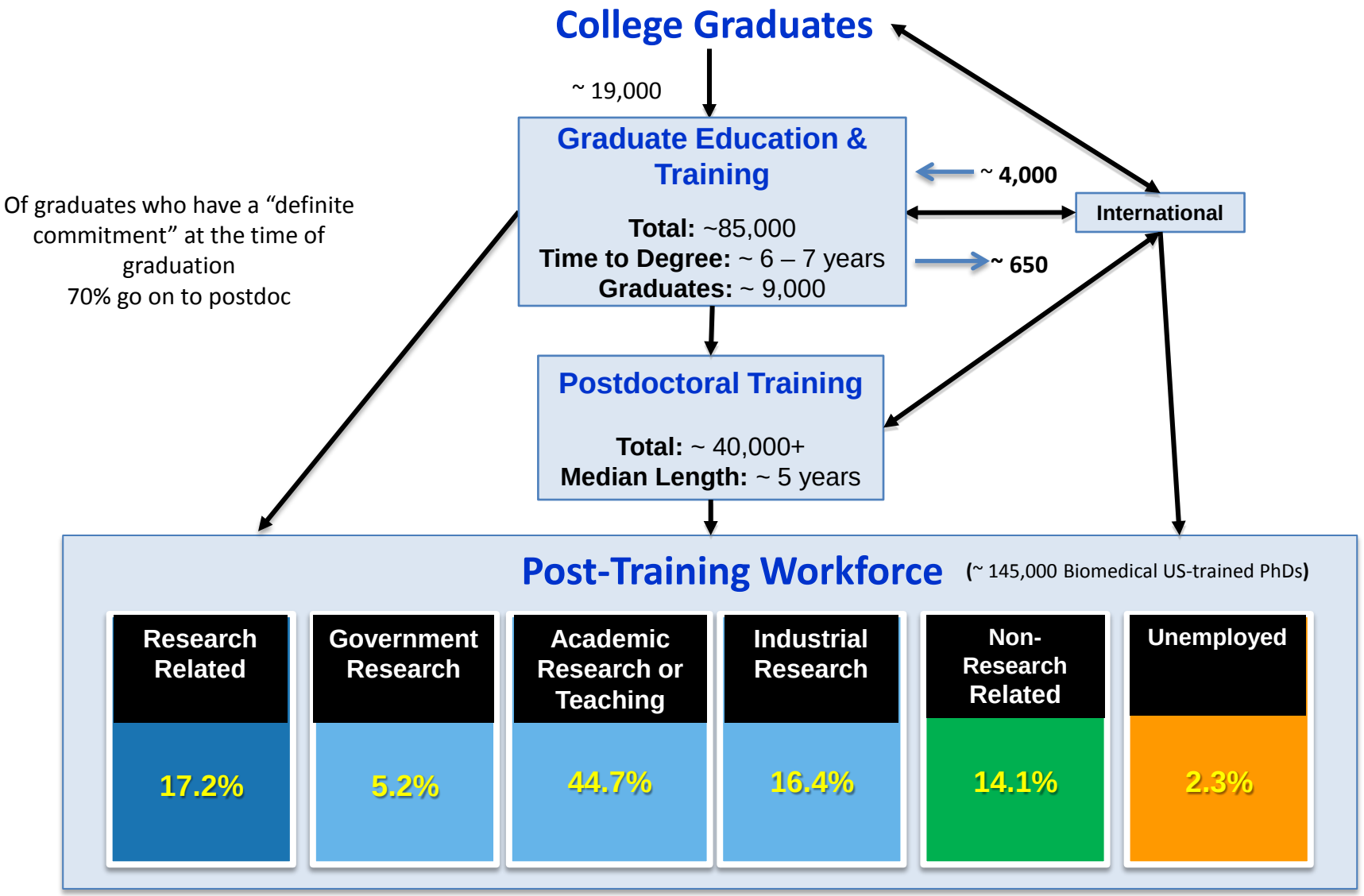
1980 & 2012



PhD Biomedical Research Workforce



Note: All data estimates come from 2011 NSF data (GSS, SED, etc.), 2011 stay rates data (Mike Finn), and the 2010 SDR. Median length of postdoc cited from Kahn & Ginther (2014). OER/OEP/DBRW

Workgroup Conclusions

Weighing all the data analyzed, the working group concluded that:

- The large upsurge in US-trained PhDs, increased influx of foreign-trained PhDs, and aging of the academic biomedical research workforce make launching a traditional, independent, academic research career increasingly difficult.
- The long training time and relatively low early-career salaries when compared to other scientific disciplines and professional careers may make the biomedical research career less attractive to the best and brightest of our young people.
- The current training programs do little to prepare people for anything besides an academic research career, despite clear evidence that a declining percentage of graduates find such positions in the future.

National Institutes of Health
Office of Extramural Research

Initiatives

- Putting individual development plans in place for all trainees
- Reducing the length of graduate training
- Offering F30s and F31s from all ICs – fully implemented for applications received after April 2014
- Increasing postdoctoral stipends – implemented in FY2014
- Considering policies on benefits
- Shortening the eligibility period and increasing support for K99/R00 – implemented for applications received after February 2014

Initiatives

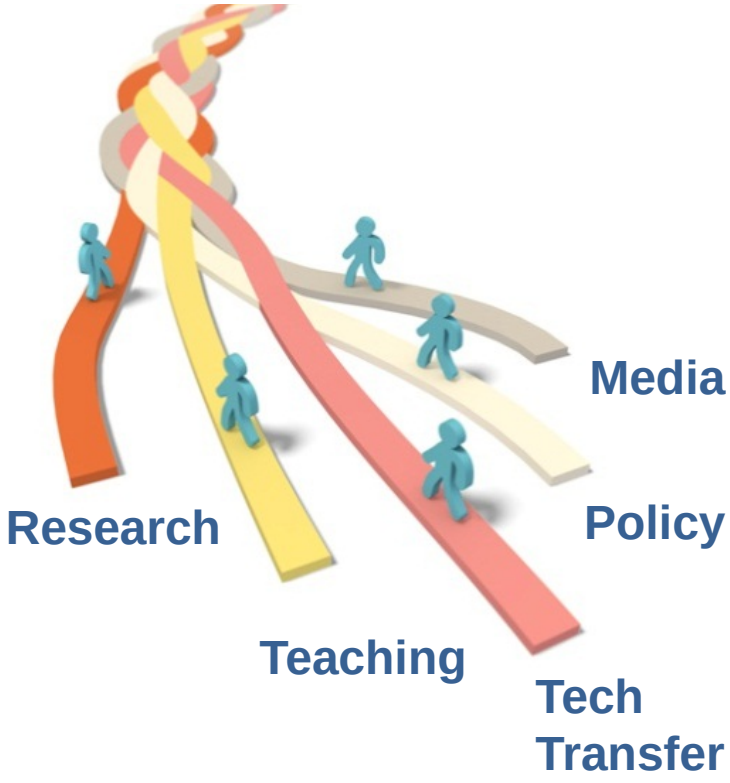
BEST

Broadening Experiences in Scientific Research

2013

2014

Innovative ways to prepare trainees for a variety of career options in the biomedical research workforce.



Trans-NIH Working Groups

- How to shorten the time to which early stage investigators reach research independence (Chair: Sally Rockey, OER)

- Identifying ways to develop more efficient and sustainable funding mechanisms and policies (Chair: Jon Lorsch, NIGMS)

Rock Talk

Helping connect you with the NIH perspective

Posted on July 17, 2014 by Sally Rockey and Francis Collins

Formula for Innovation: People + Ideas + Time

In these times of tight budgets and rapidly evolving science, we must consider new ways to invest biomedical research dollars to achieve maximum impact—to turn scientific discoveries into better health as swiftly as possible. We do this by thinking strategically about the areas of research that we support, as well as the process by which we fund that research.

Historically, most NIH-funded grants have been "project-based," which means that their applications have clearly delineated aims for what will be accomplished during a defined project period. These research project grants typically last three to five years and vary in award amount. For example, the average annual direct cost of the R01 grant—the gold standard of NIH funding—was around $282,000 in FY

Dr. Sally Rockey is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

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NIH institute considers broad shift to 'people' awards

Approach promises freedom from grant writing but could favor established researchers

By **Jocelyn Kaiser**

Fund people, not projects. That's long been the philosophy of the largest private, nonprofit U.S. biomedical research funder, the Howard Hughes Medical Institute (HHMI), but the $30 billion U.S. National Institutes of Health (NIH) has remained a bastion of project-based grants. Now, in a major shift, some NIH institutes propose to move large chunks of money away from project grants into this type of no-strings support, which is based not on a specific research plan but on an investigator's promise.

Jon Lorsch is targeting "regular outstanding researchers."

The most far-reaching proposal comes from NIH's basic research institute, the National Institute of General Medical Sciences (NIGMS). It is seeking feedback from the

at institutions around the country with 5-year awards totaling $1 million a year. Inspired by that example, in 2004 the NIH director's office launched its Pioneer Award, which now funds 70 investigators doing high-risk, high-reward research. The experiment seems to be working: Pioneer Awards produced more innovative and higher impact results, concluded a 2012 study commissioned by NIH that compared the grants with a matched set of NIH's standard R01 project-based grants (see table).

NIH is now encouraging its 27 institutes and centers to launch their own people awards. The objective is to "unbridle scientists a bit," allowing them to "step off the grant treadmill," says Sally Rockey, NIH's deputy director for extramural research.

Furthest along is the National Cancer Institute (NCI), which last month announced

New Approaches to Supporting Science

- NIH is piloting the concept of awarding longer grants that provide more stable support for investigators at all career stages.
- Each Institute and Center will decide the appropriate size and duration of their awards.
- Applications will not require specific aims in the R01 format; investigators will describe their research plans and demonstrate how they will translate their prior accomplishments into future research approaches.

New Approaches to Supporting Science

- **PAR-14-267: NCI Outstanding Investigator Award (R35)**
  - to provide long-term support to experienced investigators with outstanding records of research productivity
  - to allow investigators the opportunity to take greater risks, be more adventurous in their lines of inquiry
  - up to 7 years of support; $600K in direct costs
- **RFA-GM-16-002: NIGMS Maximizing Investigators' Research Award (R35)**
  - to increase the stability of funding for NIGMS-supported investigators
  - to increase flexibility for investigators to follow important new research directions
  - up 5 years of support; $750K direct costs

Rock Talk

Helping connect you with the NIH perspective

Posted on February 3, 2015 by Sally Rockey

Seeking Your Input on Sustaining the Workforce Through an Emeritus Award

From enhancing diversity to supporting training in emerging fields, over the past three years NIH has continued to examine the needs of the biomedical workforce and create initiatives that will sustain the amazing work being performed by you, the extramural research community.

Our efforts place a lot of focus on trainees and early stage investigators through policy changes and new programs, but there are two sides to every equation. We have many well-established research programs run by senior investigators. We want to explore how we can help senior investigators who wish to transition out of a position that relies on funding from NIH research grants, and facilitate the transfer of their work, knowledge and resources to junior colleagues. There are many high impact ways in which established investigators can contribute to science. I've written before about the importance of mentorship for example.

Dr. Sally Rockey is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

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Sustaining Discovery in Biological and Medical Sciences

A Framework for Discussion

2.10: Research sponsors should consider creating a transition award for senior investigators

FASEB

Federation of American Societies for Experimental Biology

Request for Information: A Potential Emeritus Award for Senior Researchers

- **NOT-OD-15-064**
  Release Date: February 3, 2015
  Response Date: March 6, 2015

- Could allow a senior investigator to transition to a new role, such as full time teaching

- Could permit a senior investigator to form a partnership with a junior faculty member in order to hand off his or her line of research inquiry

NIH proposal to cr
scientists hits a ne

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Jocelyn is a staff writer for *Science* magazine.

Email Jocelyn

By Jocelyn Kaise

A seemingly inn
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Deputy Director for Extramural Rese
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used to close down a lab, the notice

So far, most of the more than 120 co
other blogs (see DrugMonkey, Data

Neuro Policy @DCNeuroPolicy · Feb 5
Interesting discussions on **#emeritusNIHGrant** idea. Every comment I've seen has been negative. Bad policy? nexus.od.nih.gov/all/2015/02/03…

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Doctor PMS @Doctor_PMS · Feb 5
109 now. Still not enough. RT @drugmonkeyblog: 90 mostly opposed comments on **#emeritusNIHGrant** debacle. That's it? nexus.od.nih.gov/all/2015/02/03…

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Boer Deng @boerdeng · Feb 5
Anyone have thoughts on **#emeritusnihgrant** willing to be share w/ Nature 4 a story? Pls DM or email: boer[dot]deng[at]us[dot]nature[dot]com

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Drug Monkey @drugmonkeyblog · Feb 5
#emeritusRFI **#emeritusNIHGrant** RT @SenSanders: Some people continue to defend trickle-down theories... - @Pontifex

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Manny Ares @RiboGuy · Feb 5
That riff-raff study section not scoring your grants highly based on your track record? **#emeritusNIHGrant**

4 4

Manny Ares @RiboGuy · Feb 5
Having trouble getting into the lab before 10:30 AM? **#emeritusNIHGrant**

Rock Talk

Helping connect you with the NIH perspective

Posted on April 2, 2015 by Jon Lorsch and Sally Rockey

Give Input on Strategies for Optimizing the Impact and Sustainability of Biomedical Research

Dr. Jon Lorsch is director of NIH's National Institute of General Medical Sciences and a frequent contributor to the NIGMS Feedback Loop blog.

An important, recurring discussion topic on our blogs is ways to maximize the impact and sustainability of NIH-funded biomedical research. In 2011, a *Rock Talk* post on managing NIH's budget in fiscally challenging times solicited many comments and led, in part, to an NIH-wide policy on special council review for applications from PIs who have more than $1 million in NIH funding. We have

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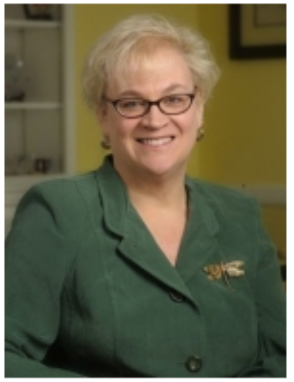
- A Shared Responsibility
- Comment on Proposed Pilot to Support NIGMS



Dr. Sally Rockey is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

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RFI: Optimizing Funding Policies and Other Strategies to Improve the Impact and Sustainability of Biomedical Research

- **NOT-OD-15-084**
  Release Date: April 2, 2015
  Response Date: May 17, 2015
- Key issues that currently limit the impact of NIH's funding for biomedical research and challenge the sustainability of the biomedical research enterprise.
- Ideas about adjusting current funding policies to ensure both continued impact and sustainability of the NIH-supported research enterprise. We welcome responses that point to specific strengths or weaknesses in current policies and suggest how we can build on or improve them.
- Ideas for new policies, strategies, and other approaches that would increase the impact and sustainability of NIH-funded biomedical research.

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grants.nih.gov/grants/oer.htm

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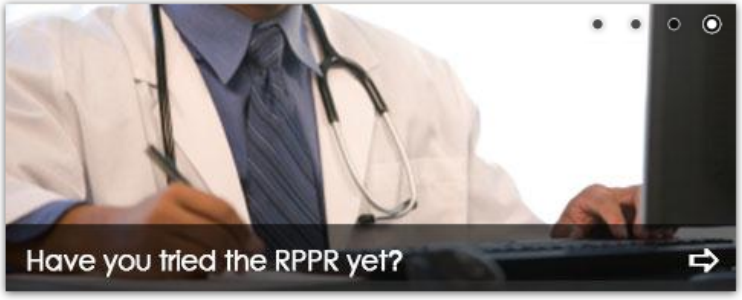

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Rock Talk

NEW New Blog on the Block
When Disaster Strikes
Clearing Up Confusion about Postdoc Salaries and Training Activities

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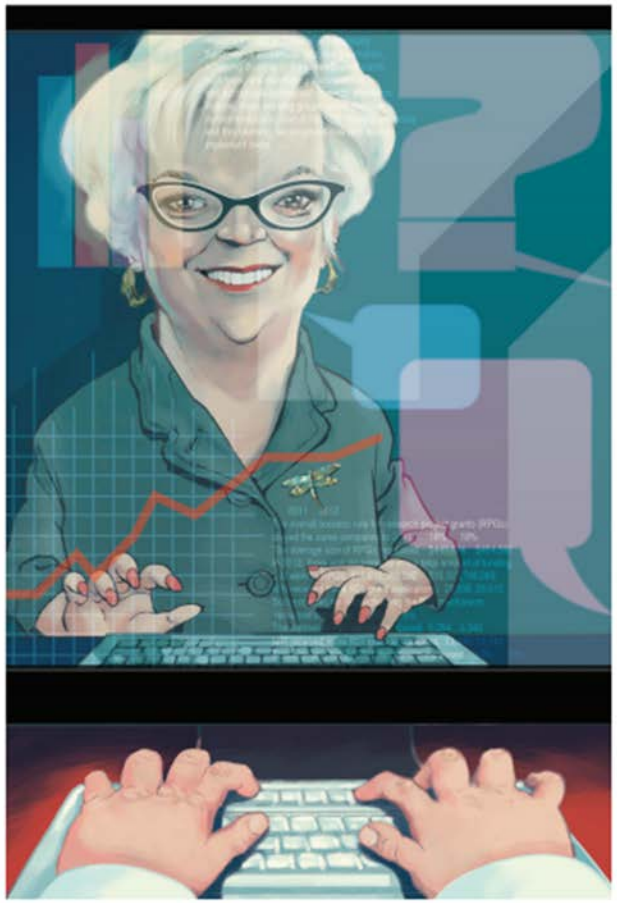

Two years of blogging the NIH

Sally Rockey, deputy director for extramural research at the US National Institutes of Health, reflects on the second anniversary of her precedent-setting blog.

In 2010, a few of my staff members began pressuring me to start a blog. Although my friends and colleagues will attest that I'm not a sh
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decisions, seemed like the right
On 19 January 2011, I launch
Talk blog (http://nexus.od.nih.g
talk). Two years later, I'm delighte
(even though I have taken heat for
many exclamation marks!). As of 2
2013, I've written 107 blog posts, av
about 40,000 page views a month. A steady stream of comments keeps me on my toes (see 'Top ten hits'). For the first time, the NIH was presenting data from all of its institutes and centres, and was sharing its analysis of funding trends on a forum where scientists could
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tions have increased since the 1980s. Within two weeks, the post generated nearly 90 comments, about everything from the ethics of training non-US scientists to the importance of including more MD-trained investigators.

A SENSE OF COMMUNITY

We learned a lot about our constituents' interests and needs through the blog, and we have been able to highlight behind-the-scenes data, actively engage the community in policy-making and provide insight into our decisions. Without public input, effective and impactful policy cannot be created. My blogging experience has convinced me that using social-media platforms is one effective way for science-funding agencies

Get Connected to the NIH Blog

I'm Tweeting!!
@RockTalking

http://nexus.od.nih.gov/all/rock-talk

NIH National Institutes of Health
Office of Extramural Research