NIH Update

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health
Council of Councils
September 1, 2017





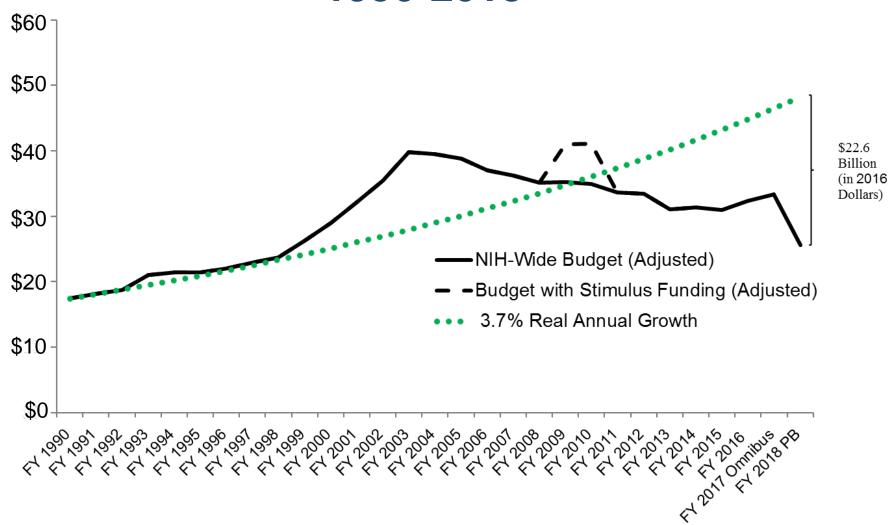
Topics

- Budget Update
- Next Generation Researchers Initiative
- NIH Opioid Research Initiative: Using Research to End the Opioid Crisis
- Science Advances





National Institutes of Health Funding 1990-2018



Note: The 3.7 % Real Annual Growth is based on real compound annual growth between 1971 and 1997. Dollar values are adjusted to 2016 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 (January 19, 2017)

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YOUNG, TALENTED AND FED-UP

BY KENDALL POWELL

artin Tingley was coming undone. It was late autumn 2014, just over a year into his assistant-professor job at Pennsylvania State University in State College, and he was on an eight-hour drive home after visiting his wife in Boston. He was stressed, exhausted and close to tears. As the traffic zipped past in the dark hours of the early morning, the headlights gave him the surreal feeling that he was inside a video game.

Usually, Tingley thought of himself as a "pretty stoic guy" - and on paper, his career was going well. He'd completed a master's degree in statistics and a PhD in Earth science, both at Harvard University. With these, and four years of postdoctoral experience, he had landed a rare tenure-track faculty position. He thought he would soon be successfully combining statistics and climate science to produce the type of interdisciplinary research that funding agencies say they want.

In fact, scientific life was proving tough. He found himself working 60-80 hours per week doing teaching and research. His startup funding had run out, he had yet to secure a major grant and, according to a practice com-

Scientists starting labs say that they are under historically high pressure to publish, secure funding and earn permanent positions leaving precious little time for actual research.

Young scientists and senior scientists alike feel an acute pressure to publish and are weighed down by a growing bureaucratic burden, with little administrative support. They are largely judged on their record of publishing and of winning grants - but without clear targets, they find themselves endlessly churning out paper after paper. The crucial question is whether this is harming science and scientists. Bruce Alberts, a prominent biochemist at the University of California, San Francisco, and former president of the US National Academy of Sciences, says that it is. The current hyper-competitive atmosphere is stifling creativity and pushing scientists "to do mediocre science", he says - work that is safe and uninteresting. "We've got to reward people who do something differently."

Our informal survey suggests that the situation is already making research an unwelcoming career. "Frankly, the job of being a principal investigator and running a lab just looks horrible," wrote one neuroscientist from the United States. Tingley wouldn't disagree.

FUNDING FIGHT

an opportunity to direct their own creative, Tingley has always had broad interests. At

Nature 2016;538:446-9



"The funding cycle is brutal."

MARTIN TINGLEY

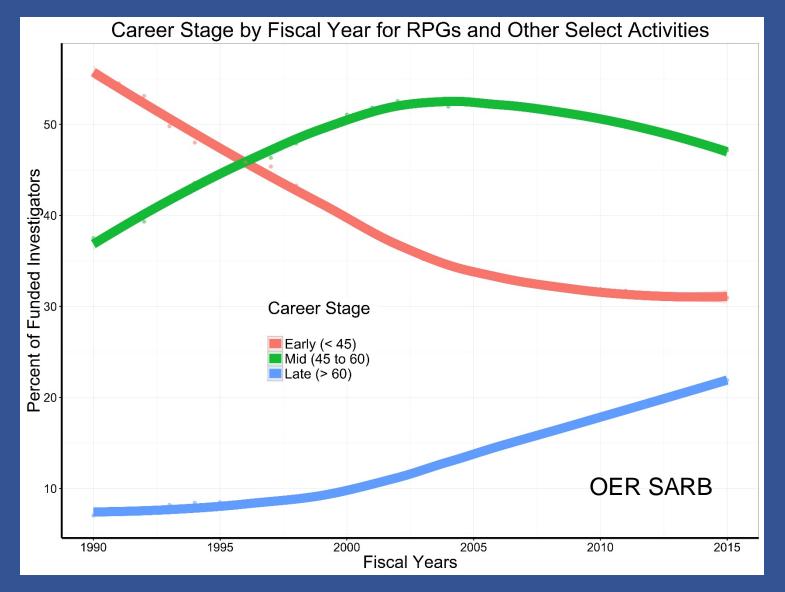
What They're Saying

SUFFERING IN SCIENCE

We asked young scientists to tell us their concerns. This is what they said.

- Desperate pursuit of grants
- No time for science
- Extreme competition ... to cut corners
- Dependence on senior scientists
- Administrative overload ... No help
- Long hours

Is This True?



Future of fundamental discovery in US biomedical research

Michael Levitt^{a,1} and Jonathan M. Levitt^b

"What caused the drop in number of young scientists? Older grantees are getting money at the expense of younger grantees ... Study sections are biased ..."

Congressional Input



Legislation

H.R.34 - 21st Century Cures Act

114th Congress (2015-2016) | Get alerts

Subtitle C—Supporting Young Emerging Scientists

SEC. 2021. INVESTING IN THE NEXT GENERATION OF RESEARCHERS.

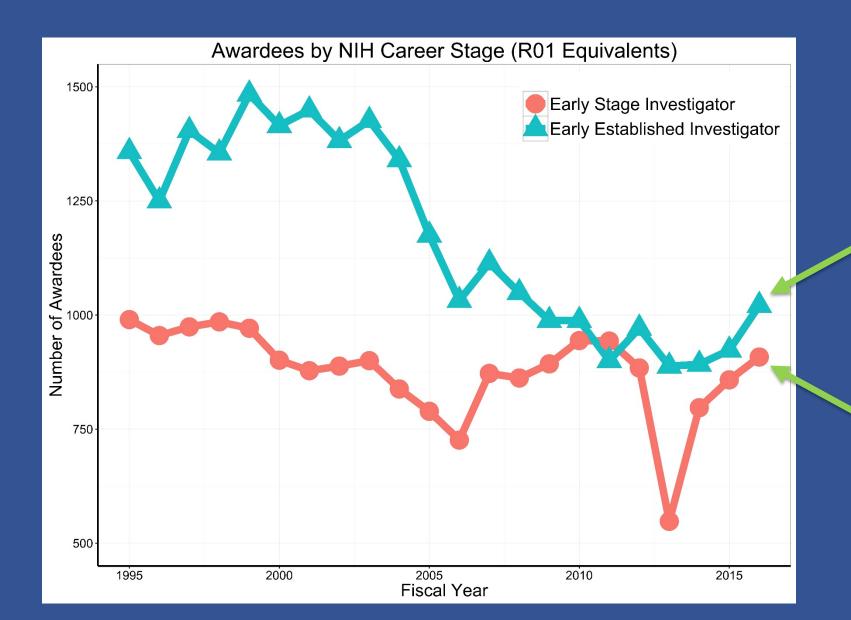
(a) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

"SEC. 404M. NEXT GENERATION OF RESEARCHERS.

What the Law Calls For

"The Director of the National Institutes of Health shall ... develop, modify, or prioritize policies, as needed ... to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity."

Next-Gen Researchers Initiative



Increase EEI Awardees by ~200

Increase ESI Awardees by ~200

Next-Gen Researcher Considerations

- Where will the money (\$210M in 2017) come from?
 - Adjustment of other IC Priorities
 - Include existing mechanisms: R56, R35, NIAMS STAR
- Monitoring will be essential
 - Workforce size and diversity
 - Scientific excellence and outcome
 - Opportunity for further development of metrics
 - Working Group for the Advisory Committee to the Director

NIH Guide Notice

Policy Supporting the Next Generation Researchers Initiative

Notice Number: NOT-OD-17-101

Key Dates

Release Date: August 31, 2017

Implementation Date: August 31, 2017

Related Announcements

NOT-OD-08-121- Rescinded

NOT-OD-09-013 - Rescinded

NOT-OD-09-134 - Rescinded

Issued by

National Institutes of Health (NIH)

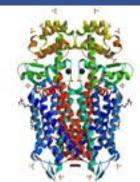
Purpose

This notice announces a new policy designed to invest in the next generation of researchers; this policy implements, in part, Section 2021 of the 21st Century Cures Act ¹. This policy supersedes previous notices on new and early stage investigators (NOT-OD-08-121, NOT-OD-09-013 and NOT-OD-09-134).

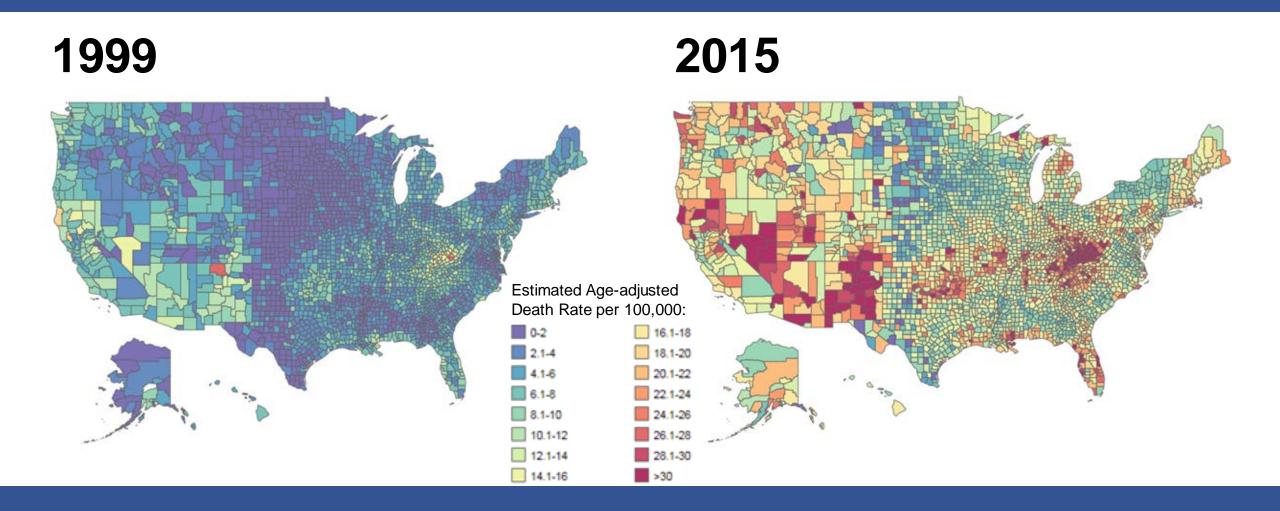
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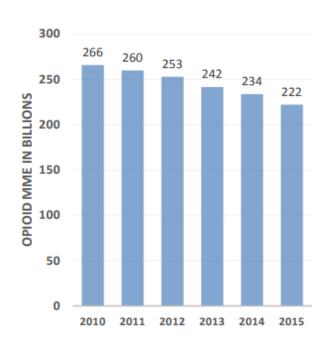


The Crisis: Overdose Death Rates



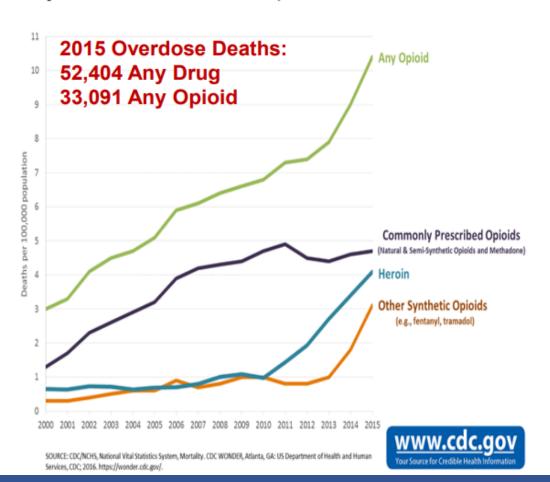
Opioid Prescriptions have started to Decrease but Opioids Fatalities are still Increasing

Opioid morphine milligram equivalents (MME) dispensed fell by over 15% from 2010-2015



Source: IMS Health, U.S. Outpatient Retail Setting

Opioid OD Deaths US, 2000-2015



Challenges of the Opioid Epidemic

- 25.5 million adults have pain every day
 - Opioids are overprescribed, not effective for *chronic* pain
- More than 2 million Americans are addicted to opioids
 - Most started with prescription medicines
- Medication-Assisted Treatment (MAT) are available for opioid use disorders and to prevent/reverse overdose
 - But MATs are drastically underutilized
 - Duration of treatment needed is not well understood
- Research has revolutionized our understanding of addiction and pain
 - But alternatives to treat addiction and overdose are limited
 - And new, non-addictive pain medicines are urgently needed

Scientific Strategies for Combating the Opioid Epidemic

	SHORT-TERM STRATEGIES	INTERMEDIATE STRATEGIES	LONG-TERM STRATEGIES
OVERDOSE PREVENTION	Stronger opioid antagonist formulations		
	Novel medications (e.g., 5-HT1A agonists, ampakines)		
& REVERSAL		Phrenic-nerve stimulation device	
		Technologies to detect overdose &	alert help or autoinject naloxone
	New formulations of existing		
TREATMENT OF OPIOID-USE DISORDERS	Repurposing approved therapies (e.g., lorcaserin)		
		Novel medications targeting no	
			monoclonal antibodies
		Brain-stimulation technolog	ies
	Opioid formulations with abus	e-deterrent properties	
TREATMENT OF CHRONIC PAIN	MOR-biased agonists		
		Cannabinoids	
	Novel or repurposed medications targeting pathophysiology (e.g., sodium-channel blockers)		
	Monoclonal antibodies		
		Brain-stimulation technologies	
			*Gene therapies
			*Progenitor cell therapies
Adapted from Volkow & Collins,			Precision medicine
NEJM, 2017.		Biomarkers	

Administration Priorities

- President's Commission on Combating Drug Addiction and the Opioid Crisis
- Recommendation from interim report: "Instruct the NIH to begin to immediately work with the pharmaceutical industry in two areas; the development of additional MAT options and the development of new, non-opioid pain relievers based on research to clarify the biology of pain."
- NIH is pursuing two Public-Private Partnerships to:
 - Develop New Formulations for Treatment of Addiction and Overdose
 - Accelerate Development of New Non-addictive Pain Therapies



President's Commission on Combating Drug Addiction and the Opioid Crisis



Using Science to End the Opioid Crisis: A Public Private Initiative

Pain

Safe, effective, non-addictive strategies to manage pain

Addiction

Innovative approaches to treat opioid addiction, prevent/ reverse overdose

Test Effective Treatments

National research network to test new therapies, preventative strategies

Stakeholders

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Science Advances

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NIH DIRECTOR'S BLOG

Another Milestone in the Cystic Fibrosi

Posted on July 20, 2017 by Dr. Francis Collins



Caption: Two-year-old Avalyn is among the cystic fibrosis patients wh targeted drugs.

Credit: Brittany Mahoney

NIH DIRECTOR'S BLOG

FDA Approves First CAR-T Cell Therapy for Pediatric Acute Lymphoblastic Leukemia

Posted on August 30, 2017 by Dr. Francis Collins



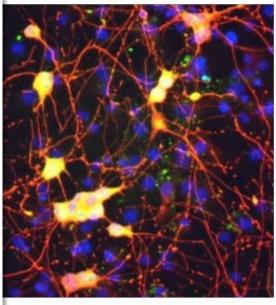
Caption: Cancer survivor Emily Whitehead with her dog Lucy.

Credit: Emily Whitehead Foundation

CTOR'S BLOG

nds: A Transcriptional "Periodic Table" leurons

7 by Dr. Francis Collins



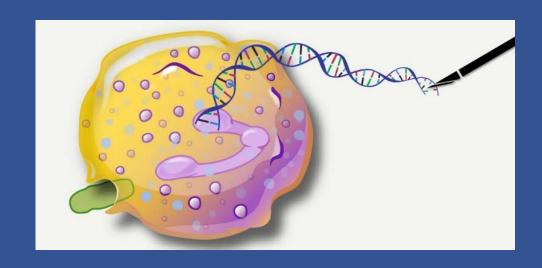
ists converted into induced neuronal cells, showing neuronal I (blue) and the neural protein tau (yellow). Scripps Research institute, La Jolla, CA

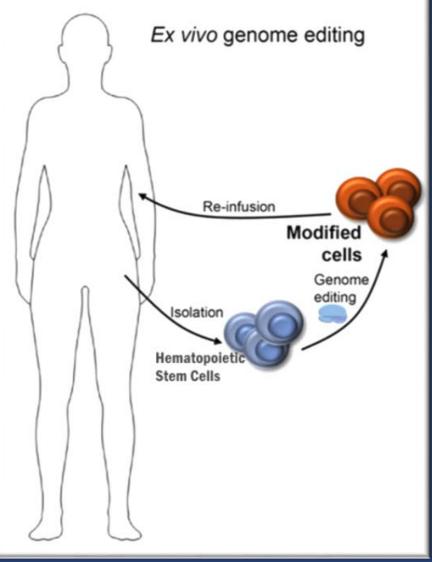
Science Advances

Making Somatic Cell Genome Editing Therapies a Reality

A Common Fund Planning Workshop

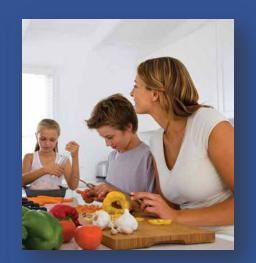
July 24, 2017 Building One, Wilson Hall, NIH Campus Bethesda, MD













Turning Discovery Into Health

directorsblog.nih.gov





