

Robin Barr Keynote Address

FDA Approval and Aging:

What is the Real Bottleneck for Translational Geroscience

Norman E. Sharpless, MD

Co-Founder and Managing Director, Jupiter BioVentures

Professor of Cancer Policy and Innovation, The University of North Carolina School of Medicine

November, 2025

Robin Barr

- Robin Barr, PhD was the Director of the Division of Extramural Affairs at the NIA until he retired in 2020 after 33 years at NIA.
- Fierce advocate of training: He oversaw training initiatives, anticipated the need for new kinds of training, and helped to steer NIH overall policy.
- Substantially expanded NIA's career development awards program.
- Dr. Barr was instrumental in transitioning the Beeson Program from private sponsorship to its unique current public-private partnership.



My Back Story



Went straight to medical school at UNC



Took year off between second and third year to work in a lab at NIH through the Howard Hughes Medical Institute (where I learned I wanted to be a scientist)



Did residency in internal medicine at Massachusetts General Hospital, then fellowship in oncology at Dana Farber-Partners; both in Boston



Got married as a fellow ('95) and had two kids in Boston



Joined UNC SOM faculty in 2002, became UNC Cancer Center Director in 2014

Ran a Lab in the Cancer Center at UNC



Circular RNAs are abundant, conserved, and associated with ALU repeats

WILLIAM R. JECK,^{1,2} JESSICA A. SORRENTINO,³ KAI WANG,⁴ MICHAEL K. SLEVIN,⁵ CHRISTIN E. BURD,¹ JINZE LIU,⁴ WILLIAM F. MARZLUFF,^{5,6} and NORMAN E. SHARPLESS^{1,2,3,7,8}

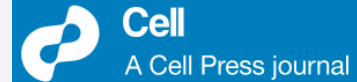
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Senescence in Health and Disease

[Shenghui He](#)^{1,2} · [Norman E. Sharpless](#)^{1,2}  

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ARTICLE

Multiple Roles of Cyclin-Dependent Kinase 4/6 Inhibitors in Cancer Therapy

Patrick J. Roberts, John E. Bisi, Jay C. Strum, Austin J. Combest, David B. Darr, Jerry E. Usary, William C. Zamboni, Kwok-Kin Wong, Charles M. Perou, Norman E. Sharpless

Manuscript received May 4, 2011; revised December 13, 2011; accepted December 28, 2011.

Correspondence to: Norman E. Sharpless, MD, The Lineberger Comprehensive Cancer Center, University of North Carolina School of Medicine, CB 7295, Chapel Hill, NC 27599 (e-mail: nes@med.unc.edu).

Evolution of Senescence Research:

- Senescence has gotten much bigger.
- The molecular and cellular biology has gotten a lot better (but the physiology is still not all there).
- It's not all telomeres.
- It used to be SASP vs. Replicative arrest,
but now there are other possibilities.
- Senescence used to be all bad,
but now there are other possibilities.
- It has started to draw translational interest.
- Judy Campisi no longer runs the meetings....



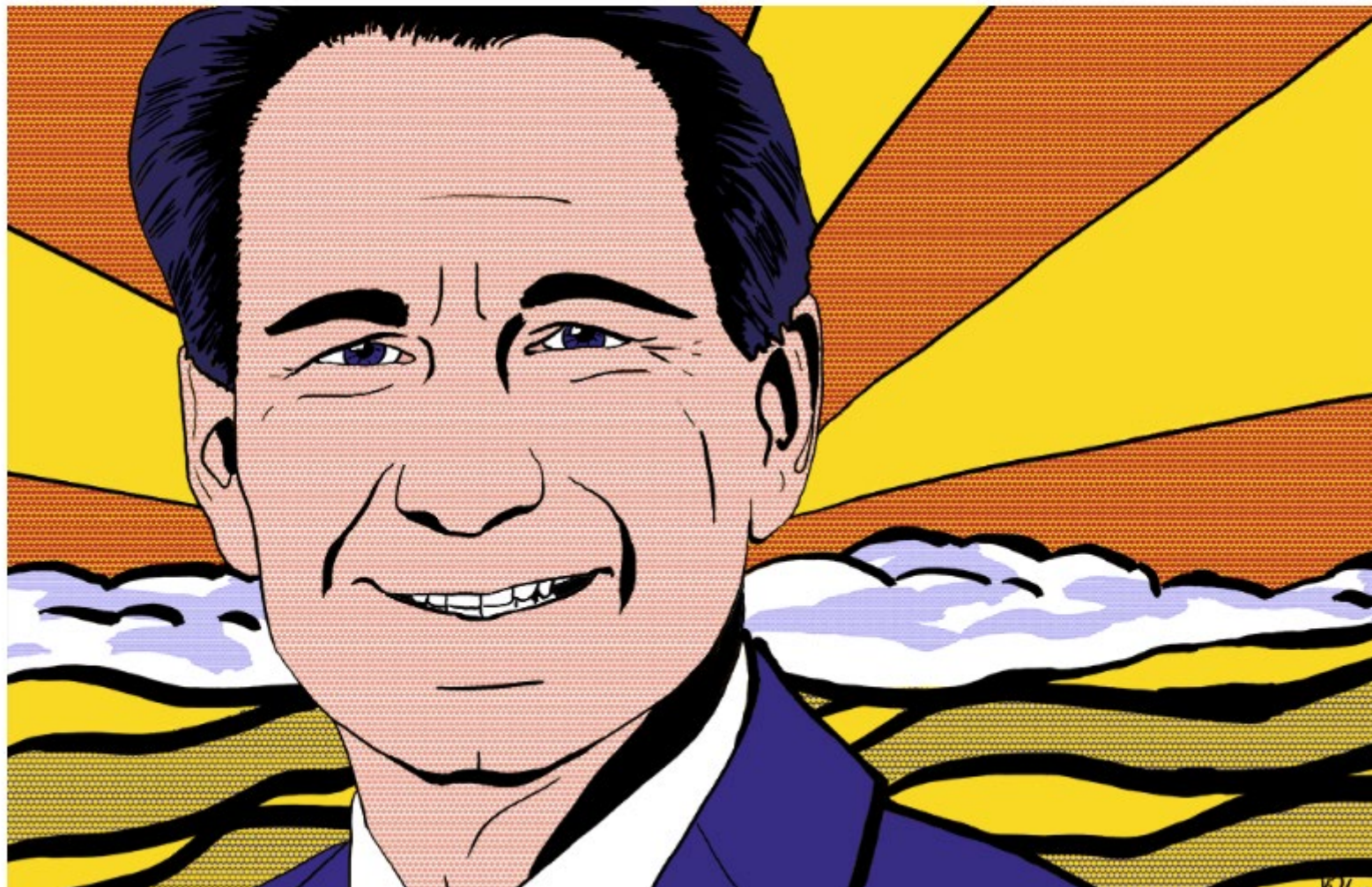
G1 Therapeutics (from Idea to IPO to FDA approval)



Ned Sharpless, Trump's choice for NCI director, described as erudite scientist whose expertise spans basic, clinical research

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NIH/NCI
(2017-2022)



FDA (2019)

The New York Times

National Cancer Chief, Ned Sharpless, Named F.D.A.'s Acting Commissioner

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Dr. Norman E. Sharpless was named acting commissioner of the Food and Drug Administration on Tuesday. For the last 18 months, he has been the director of the National Cancer Institute. Tom Williams/CQ Roll Call



POLITICS

STAT+

A believer in biotech and big data: How Ned Sharpless vaulted to the top of the FDA



By [Lev Facher](#) and [Kate Sheridan](#) March 14, 2019

[Reprints](#)



Ned Sharpless (left), joined by his wife, Julie Sharpless, is sworn in as director of the National Cancer Institute.

NIH

WASHINGTON — Almost immediately after beginning his Bethesda, Md., day job as the nation's top cancer researcher, Ned Sharpless built a roughly 7-mile detour into his weekly routine: a sojourn to the Food and Drug Administration campus for a pickup basketball game.

Whether or not the networking was intentional, Sharpless will soon be spending far more time with the FDA oncologists who once broke his finger. When Scott Gottlieb steps down after a nearly two-year tenure next month, Sharpless will take the helm of that agency, at least in the short term.



SARA HARRISON SCIENCE SEP 25, 2019 2:38 PM

The FDA Tells Congress E-Cigarettes Are Unsafe—and Illegal

At a hearing, politicians spar over vaping's lax enforcement, while Juul and other e-cigarette makers face a growing



The FDA's acting commissioner, Norman "Ned" Sharpless, fielded questions today from frustrated lawmakers. PHOTOGRAPH: WIN MCNAMEE/GETTY IMAGES

Two Administrations and COVID:



Now: Jupiter BioVentures, UNC SOM and BoD Work

STAT+ | BIOTECH

Former NCI chief and serial biotech entrepreneur raise \$70 million to start companies that fail fast

'Ned' Sharpless and 'Ned' David form Jupiter Bioventures to test ideas with efficiency



Norman Sharpless, left, and Nathaniel David, now better known as "the Neds." Courtesy Jupiter Bioventures



KARIUS



Nucleus
RadioPharma

Problems for US BioMedical Progress



Tight Budgets
and Spiraling
Research Costs



Waning
Congressional
support



Persistent
Disparities (esp.
Rural)



Regulatory
Backsliding

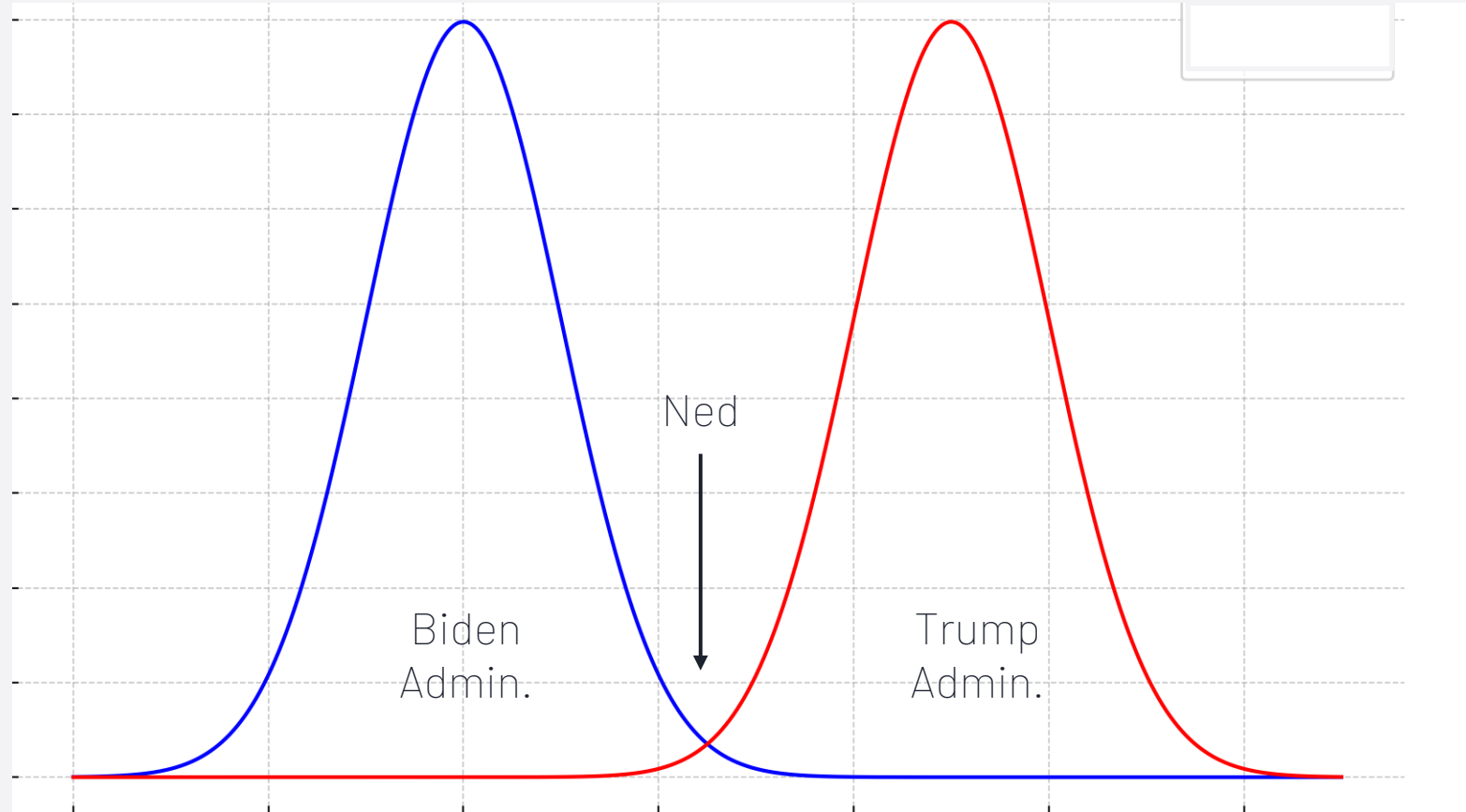


Pandemic
Hangover



Antipathy to
industry

My Politics:



Images that Explain DC in 2025:



The government will spend **\$86 trillion** over the next decade.

And lawmakers are complaining about reducing spending by \$2 trillion?

\$86 Trillion Ten-Year Spending	\$2 Trillion Reconciliation Cuts
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That doesn't add up.

Committee on
Responsible Federal Budget

1. There Are Great People in Federal Government:



Janet Woodcock,
CDER/FDA



Mike Lauer,
OER/NIH



Alex Azar,
HHS



Jim Cherry
FNL/NIH

2. The NIH Remains Very Popular in Congress



"We urge you to stop playing political games with the lifesaving work of the NIH and to allow NIH research to continue uninterrupted."

--Patty Murray (D-WA)



"One of the big problems we've had in recent years is when that NIH budget doesn't grow. You're really sending a message to younger researchers, 'There's not a future for you.'"

--Tom Cole (R-OK)

3. We Will Get Through This

- Focus on the things that matter (e.g. the NIH budget)
- Conserve political capital
- Work as teams not individuals
- Congress has awesome power and will use it
- Midterms are just 12 months away....

Beyond NIH Funding, Ongoing Policy Discussions

FDA:

- Accelerated Approval
- Tobacco Cessation products
- Guidance on lab developed tests
- AI-enabled devices

HHS and Executive Branch:

- The Inflation Reduction Act (IRA)
- CMS coverage decisions
- Research integrity at NIH
- Vaccine policy
- March-In Rights

Congress

- VALID Act: Regulation of Diagnostics
- PASTEUR Act: Funding to address anti-microbial resistance
- CDMRP (DoD Science funding)
- MCED Coverage Act
- Pandemic and All-Hazards Preparedness Act (PAHPA) Reauthorization
- Fixes to the IRA (e.g. the Epic Act)
- AI Legislation (e.g. Health Tech Act)
- The BioSecure Act
- Patent Thicket Reform Bill

THE VIEWS EXPRESSED BY CONTRIBUTORS ARE THEIR OWN AND NOT THE VIEW OF THE HILL

Humans Can Start Living Longer—Once the FDA Does

C|
spBY AMY **Popular
Mechanics**

As billionaires race to fund anti-aging projects, a much-discussed trial goes overlooked

By [Megan Molteni](#) Aug. 9, 2022**STAT**[Reprints](#)

The biggest obstacle they had was the Food and Drug Administration. The federal regulator adheres to a “one disease, one drug” model of approval. And because the agency does not recognize aging as a disease, there’s no path forward for a drug to treat it. And even if there was, it’s impractical to do a lifespan study — it would take decades and be astronomically expensive.

“Disease” versus “Indication”

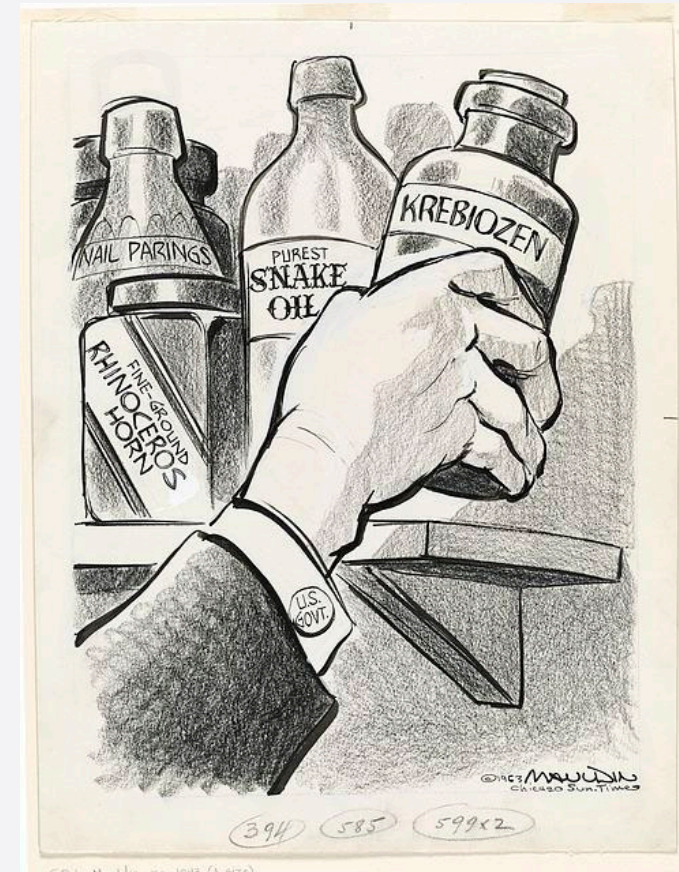
- FDA has to follow the law.
- The *Food, Drug and Cosmetics Act (amend 1962)* says the standard for the approval of a new medicine is that it is “safe and effective *for intended use based on substantial evidence.*”
- “Intended use” is the “indication”, all medicines are approved for an indication(s) which are listed on their label.
- Indications are not necessarily “diseases” (e.g. nicotine addiction, elevated intraocular pressure, osteoporosis).
- The list of approvable indications is not static (e.g. *hyperlipidemia, obesity, hypertension* were all things where FDA had to be convinced these were approvable).

Relying on this trope is bad:

1. It suggests the translational geoscience community is unserious, in that its leaders lack an understanding of how the FDA works.
2. It is not persuasive in that it is not going to influence FDA practice or increase Congressional support for NIA / NIH.
3. It is self-serving in that it attempts to place the blame for our lack of progress on a federal bureaucracy rather than on our own lack of scientific progress.

A Word of Caution

- At main headquarters in White Oak, the FDA has a historical archive and even a small museum with rotating exhibits. <https://www.fda.gov/news-events/fda-voices/forward-past-fdas-new-history-exhibit>
- It includes information about some of the heroes of the FDA (Alma Hayden, Harvey Wiley etc), but also literally thousands of absurd to dangerous frauds advertised as cures.



It's A Thin Line: Science vs. Science Fraud

- It is dangerous to think the line between scientist and charlatan is clear and easily detected in real time.
- As geroscience research moves from rodents to humans, it is worth reflecting on this history.
- Human trials done in an unserious manner without modern endpoints, consultation with regulators and clear scientific rationale will hurt the field.



Life Advice:

- **Family:** Find a life partner, I recommend kids, work-life balance
- **Fitness:** Stay in shape, cardio lifelong and strength training after 40
- **Political:** Realize that a lot of what you see on the internet is fake. Wisdom does not lie solely within either political party.
- **Professional:** Get paid for something that interests you, and find out how to have agency in your role
- **Be a good employee, but be realistic:** Large academic institutions are wonderful but have flaws and won't love you back.