WHITE SHEET ON THE IMPORTANCE OF NIH FUNDING FOR BIOMEDICAL RESEARCH

The crisis at NIH has reached a critical point. Without immediate action, we risk causing damage to the system that will not be easy to repair or rebuild.

Disbursement of NIH funding is currently effectively STOPPED, estimated at more than \$1.5B of funding removed from the US biomedical research enterprise since January. In addition, the proposal to cut "F&A", the fraction of NIH funding that supports the Facilities and Administrative infrastructure needed to do science, will cause a collapse of the US biomedical research infrastructure – one of the crown jewels of American innovation, an enormous economic engine, and the source of our health care pre-eminence world-wide.

In a very short time irreparable damage will be done to this system. We must urge the administration, Congress and other government leaders to intervene ASAP and prevent permanent damage or complete loss of our biomedical and scientific leadership in the world.

Key Bullet Points

- There is a proposal to cap "F&A" at 15%. This will all but eliminate biomedical research at academic medical centers.
- These Facilities and Administrative (F&A) costs pay for the utilities, infrastructure, cybersecurity, human subjects safety, biosafety, radiation safety, salaries for our business, compliance, maintenance, and regulatory personnel and more
- NIH F&A do NOT cover the full cost. Universities also cover up to another 30-50%.
- This NIH funding includes support of physicians, nurses, and scientists who run clinical trials, generate the infrastructure for clinical trials, and recruit patients and other participants
- Even a partial reduction in F&A will have catastrophic effects on this workforce and the progress of science. We will not be able to support clinical trials.
- NIH funding is the best Return On Investment for any government spending at 2.4-fold
- Nationally, \$47B from NIH directly supports more than 400,000 jobs and fuels a \$1.55T pharma and biotech industry with perhaps another 2-3M jobs
- > Essentially ALL new drugs have their origin in science funded by NIH
- > Privatizing science will make things *more* expensive
- A functioning NIH is essential to make progress in many chronic diseases and reduce future health care costs. Costs for Medicare and Medicaid will increase without a functioning biomedical research infrastructure in the US.

The national impact of NIH funding for jobs, economic activity, and training

- <u>NIH Funding is the best return on investment of any government spending</u>. Every \$1 of NIH funding generated approximately \$2.46 of economic activity. This is short-term. This ROI is probably closer to 10-fold long-term.
- <u>NIH funding grows the U.S. economy</u>, The \$47B investment through NIH funded biomedical research <u>fuels a \$1.55T pharma and biotech industry</u>.
- For every \$100 million of funding, NIH-supported research generates 76 patents, which create opportunities for an estimated \$598 million in further research and development.
- <u>Every state</u> and almost every congressional district received a share of NIH investment and, consequently, the economic ROI resulting from this investment
- Indeed, red states have higher ROI per dollar of NIH funding than blue states

Critical roles of NIH funded research for the private biotech industry

- Essentially ALL new drugs originate from science funded by NIH (from 2010-2019, 354/356 FDA approved drugs trace their origins to NIH funding). This NIH fundamental science acts in partnership with great scientific efforts in the private sector to make new drugs and therapies. Neither half of this partnership can work without the other.
- NIH-funded patents produce 20% more economic value than other U.S. patents.
- NIH funding directly <u>supports ~420,000 jobs</u> in the US and roughly 5x that number (at least 2M jobs) through associated private sector activities derived from NIH funded research.

The role of academic medical centers in the workforce for health care and medical research

- NIH-supported academic research centers and universities support training of 29,000 MDs and 8-10,000 PhDs per year crucial for health of Americans and for the private sector. Approximately 70-80% of these PhDs will enter non-academic jobs (i.e., the private sector).
- Pharma/biotech employs at least 2M (and as many as 3.5M) people, with perhaps 30% with a PhD or MD who trained at NIH supported academic centers
- The threat of reducing F&A funding from the NIH is <u>already leading universities to cut</u> <u>PhD programs</u>. This is an IMMEDIATE pipeline effect. Where will these jobs go? Oversees, likely to China.
- Cutting NIH funding will <u>reduce the ability to train medical students</u>, making the US more dependent on physicians trained in other countries, compounding our physician shortage nation-wide (with an outsized impact in rural America).
- <u>Clinical trials for testing new drugs and therapies will become much more difficult.</u> As many as three-quarters of Phase I clinical trials occur at academic medical centers. This will all be stopped because the physicians and scientists involved, and the infrastructure needed, will largely disappear if NIH funding is massively cut.

Reasons F&A (Facilities and Administrative) costs are needed to support NIH-funded research

- <u>Facilities costs</u>: costs of research space: electricity, water, HVAC, waste management, IT cybersecurity, building security, building maintenance and depreciation all required for the work.
- <u>Administrative costs</u>: accounting, administrative assistants, regulatory, human subjects safety oversight, environmental safety, radiation safety, other expenditures that are explicitly disallowed to be paid from direct costs (i.e., office supplies)
- Doing NIH-funded experiments without F&A support would be like expecting researchers to do their work in a garage or a warehouse (even then, there would be a need for costs for that space).
- Funding researchers' direct costs without F&A funds is like paying the players of a professional sports team without having a stadium, trainers, locker rooms, coaches, lights, pads, uniforms, or waste management.
- Even the total direct costs + current F&A costs do NOT cover the full costs of NIHfunded research. Universities already cover a large part of the costs from health care revenue in many cases (often *another* 30-50% on top of F&A), and in some cases from revenue from endowment and/or philanthropy. *Universities lose money on the research enterprise each year*.
- Endowments cannot pay these costs: "The" endowment at large universities is actually a collection of thousands (sometimes tens or hundreds of thousands) of individual, legally-binding, gift agreements that specify that: (a) the funds can only be used for the original gift-intended purpose; (b) the corpus of the fund cannot be touched; and (c) investment revenue above the spending rule (~4-5% return) must be re-invested in the corpus. To access the principle, each gift agreement would have to be taken to orphan's court to dissolve the donor-intended contract (a difficult, slow and expensive process) and this would undermine any future philanthropy since donors could never trust that their intentions with a gift would be followed. Endowments cannot solve this issue.
- Without full F&A support, research at academic medical centers will have to be cut dramatically. <u>These jobs and related industries will move rapidly overseas</u> e.g., to China. We will be unable to train the PhDs and MDs we need. We will stop creating wealth in new discoveries, new patents, new drugs and new therapies. Health care costs will *increase* as a result.

Why not move all NIH funded research to the private sector?

- Almost all new FDA approved drugs have their origin in NIH funded academic research. This "origin" is the basic knowledge created by NIH-funding. Pharma and biotech then add tremendous innovation and value, and deep *applied* science to converting those discoveries or basic knowledge into actional therapies. The point is, this is symbiotic. Neither side can do this without the other and NIH funding is the central catalyst or engine.
- The central "engine" of biomedical knowledge is publicly accessible and readily and rapidly shared to all and is one of the most powerful and most important investments to improve health and wellness and the economic power of the US in

biomedicine. This investment in public knowledge reduces duplication and waste in biomedical research.

- With these considerations <u>NIH funding is one of the MOST efficient government</u> investments.
- Consider privatizing: Company A identifies a pathway or potential drug target. Without the massive NIH-funded knowledgebase, Company A has to perform all the discovery and basic science internally to understand this new target. This is hugely expensive to build internally (it costs many times *more* to do this in pharma/biotech that in academia). Where will these costs go? To the drug price. Now consider Company B identifies the same pathway. They now need to duplicate this effort because, of course, the data generated by Company A is not shared. Costs/prices increase.

Other facts, figures, and key points

- NIH Funding is the single best return on investment for federal spending at 2.4-fold
 - $\circ~$ This is in the short-term. Maybe 10-fold in the long-term
 - Moreover of the top 10 states for NIH ROI, 9 are red states
 - (Education spending might also be in the same range, but harder to quantify. Defense spending is more like 0.7-1.4)
- Research costs universities additional funds beyond what is received from NIH. Universities invest in research endeavors not to profit, but because it is part of our mission and values. We also do it because it helps us train students and the next generation of scientists and physicians
- NIH funding is, in fact, one of **the MOST efficient things** the government does.
- Losing F&A which reflects the government's partnership with universities to support this infrastructure will crush this engine, nearly immediately push this industry to China we'll be buying our drugs from them in just a few years and will cause a major economic collapse of a very large and productive industry.
- Moreover, this is a national security threat we will lose our ability to respond to bioterror threats, we will not be able to generate new therapeutics and/or responses to emerging infections like avian flu, measles, or ebola.
- Lastly, this damage will be rapidly irreparable. You cannot rebuild this once it's gone. The infrastructure, cultures, people, wisdom and more will not come back. This is the analogy of breaking a building made of Legos versus smashing a crystal chandelier
- There's a need/desire to address "fraud and waste" in government spending. University F&A reports are already extremely detailed, documented and transparent. But we (as a system) could certainly add additional Fraud and Waste analysis in our yearly RPPR, and/or university F&A reports.
- There are 29,000 MD graduates each year in the us and overall ~1.1M doctors.

- 88% of medical schools in the US benefit from NIH funding to enhance medical education. Without this NIH funding, the medical education system will greatly suffer and produce fewer doctors in an already overwhelmed medical system.
- As an additional point, only 57% of the 1.1M doctors in the US received their degree in the US. Cutting NIH funding would make us more dependent on foreign doctors and health care providers.
- Also, of the top 20 agricultural schools in the US, 19 receive substantial NIH funding.
- Pharma employees ~2-3M directly with about 1M in R&D directly. Indirectly supports 4.9M jobs through broader economic activity. Estimated to grow by 3% over the next decade. Biotech expected to grow by over 7%
- 5000 pharma and 6000+ biotech companies (maybe more). Global biotech market ~\$1.55T. US accounts for 40% of global R&D. While some of this industry in concentrated in states like CA, NY, MA, NJ, other major centers of activity include NC, TX, FL, GA, MI, MN, MO

Resources

https://www.usaspending.gov/award/CONT_AWD_80MSFC20C0034_8000_-NONE-_-NONE-

https://www.nih.gov/about-nih/what-we-do/impact-nih-research/serving-society/directeconomic-contributions#:~:text=direct-economic-contributions--researchinvestment.&text=Each%20year%2C%20NIH%20awards%20over,approximately%20%242 .46%20of%20economic%20activity

https://www.youtube.com/watch?v=yxTDlFvkvio

https://www.unitedformedicalresearch.org/annual-economic-report/

https://www.unitedformedicalresearch.org/nih-in-your-state/pennsylvania

https://www.fiercebiotech.com/research/report-every-dollar-nih-research-fundingdoubles-economic-returns

https://usafacts.org/government-spending/

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https://www.science.org/content/blog-post/where-drugs-come-comprehensive-look

https://www.jci.org/articles/view/129122