Written questions submitted by Senator Rand Paul

1. **Congress is running a $1.7 trillion deficit. The federal debt is about 100% of GDP. To address our fiscal crisis, I have proposed legislation, the "five penny plan," to apply modest 5% spending reductions across the federal government. The NIH has a budget of $44 billion, and this year it received a budget increase of 9%. Over its lifetime, the NIH has received average annual budget increases of 11%. The economy is not growing that fast. Taxpayers' incomes are not growing that fast. Can you commit to recommending options for reducing NIH spending so that the NIH can do its part to eliminate the federal deficit?**

Response: NIH investment drives growth of the whole biomedical research enterprise. Discoveries arising from NIH-funded research provide a foundation for the U.S. biomedical industry, which contributes over $69 billion to the U.S. GDP each year and supports over 7 million jobs. As NIH Director, I commit to always being a faithful steward of taxpayer dollars, to ensure we use every penny to its fullest extent, and root out waste, fraud, and abuse to ensure fidelity to that mission.

2. **How will you address redundancies in research topics across the institutes and centers within the NIH to ensure that taxpayers receive the maximum benefit for their money?**

Response: I take seriously the stewardship of taxpayer dollars, including minimizing redundancy of research. If confirmed, I will work with Institute, Center, and Office Directors to consider strategies for research prioritization and reducing redundancy, potentially through leveraging novel technology.

3. **To compete scientifically with other advanced nations, we must not allow science to become politicized or dictated by ideology. We advance scientific knowledge by challenging prevailing assumptions, yet today it is more difficult to get an NIH grant that challenges prevailing (and politically correct) assumptions on a range of issues, including 1) the long-term health effects of puberty blockers on minors; 2) quality research on whether gender transition surgery is beneficial or harmful; 3) randomized controlled studies on the efficacy of face masks to prevent the spread of upper respiratory viral illnesses such as COVID-19; and 4) randomized controlled trials to investigate whether repeatedly getting booster vaccinations against upper respiratory viruses such as COVID-19 are effective or whether they yield diminishing returns because of immune imprinting and immune exhaustion. If confirmed, what policies will you put in place at the NIH to prevent or reduce confirmation bias in decisions about issuing research grants?**

Response: As scientists, eliminating confirmation bias is one of the most important things we can and must do in our line of work. Without challenging our preconceived notions, we risk our ability to innovate and deliver for the American people. If confirmed as NIH Director, I believe it is imperative that I model a transparent research atmosphere where colleagues feel comfortable challenging the status quo and disagreeing with one another. We must not be afraid of hard

conversations. If confirmed, I look forward to working with you to determine the best policies and practices to deliver on that mission.

4. **As a director of a research funding organization, is it appropriate for the NIH Director or any institute director within the NIH to advocate for specific public health policies or policies that may discourage open scientific debate, as scientists are afraid to contradict those that control their research funding?**

Response: This question is paramount to what it means to be a leader, both at NIH and beyond. It is the responsibility of NIH leadership across the institutes to help inform and shape the issues facing Americans health and well-being, while continuing to ensure that they foster an environment that allows for disagreement and candid discussion.

Scientists must always encourage open scientific debate and have the courage to challenge the status quo. As history has taught us, science is always changing, and we must be ready to reevaluate the conclusions that came before in light of new evidence. The most dangerous attitude in science is one that stifles our ability to question. It is my goal to be a role model in this space.

5. **A 2022 Swedish study reviewed "published data on bone development in transgender adolescents, focusing in particular on differences in age and pubertal stage at the start of puberty suppression, chosen strategy to block puberty progression, duration of puberty suppression, and the timing of re-evaluation after estradiol or testosterone administration. Results consistently indicate a negative impact of long-term puberty suppression on bone mineral density, especially at the lumbar spine, which is only partially restored after sex steroid administration. Trans girls are more vulnerable than trans boys for compromised bone health."[1] Do you believe the long-term safety of gender affirming therapy in minors, including pharmaceutical administration, has been established by the FDA?**

    a. **If not, should gender affirming therapy in minors be considered experimental and subject to FDA oversight?**
    b. **Do you believe gender affirming therapy should require the consent of a parent or legal guardian?**

Response: As current NCI Director and NIH Director nominee, I can't speak to FDA's role on this issue. If confirmed as NIH Director, my role may include providing data on gender affirming therapy and its impact, but it would not extend to the parental/guardian consent structure of personal medical decision that exist outside of NIH.

[1] Ciancia S, Dubois V, Cools M. Impact of gender-affirming treatment on bone health in transgender and gender diverse youth. Endocr Connect. 2022 Sep 28;11(11):e220280. doi: 10.1530/EC-22-0280. PMID: 36048500; PMCID: PMC9578106.

6. **Does the NIH fund, request, direct, and/or otherwise facilitate classified life sciences research?**

Response: To my knowledge as NCI Director, NIH does not fund, request, direct, or otherwise facilitate classified life sciences research.

7. **It is widely accepted that pandemics can come from nature, from laboratory accidents, or from deliberate releases by humans. Are you aware of the NIH or any other agency performing a formal cost-benefit analysis to inform decisions on whether to create or publicly identify a new potential pandemic pathogen?**

Response: As NCI Director, I am not aware of the NIH or any other agency performing such an analysis.

8. **In the past, the NIH has failed to fully comply with its requirements for oversight of enhanced potential pandemic pathogens research mandated by the HHS P3CO Framework. If confirmed, how will you ensure that enhanced potential pandemic pathogens research proposals are forwarded to HHS for the risk-benefit and risk-mitigation review mandated by the HHS P3CO Framework, and how will you ensure that officials who failed to do so under your predecessors are held accountable?**

Response: Potential pandemic pathogen research stands to achieve great benefit for people by allowing us to respond immediately and save lives, but it also has risk. If confirmed as NIH Director, I am committed to adhering to all relevant oversight policies and protocols for programs that engage in this kind of research, to make sure that they are conducted safely and achieve the benefit we know we can see for the American people.

9. **Do you believe federal oversight of synthetic bioengineering gain-of-function research is adequate? If not, what reforms would you like to see?**

Response: I believe we can and must continually revisit and review our policies as science advances to ensure that we are identifying areas for improvement. If confirmed as NIH Director, I look forward to reviewing our polices and identifying any areas for reform.

10. **If Congress finds that the COVID-19 pandemic originated from a laboratory-acquired infection of a virus that had been part of gain-of-function experiments, would you support a ban on viral gain-of-function research funding by the NIH? If not, why not?**

Response: I am committed to working with Congress on all efforts to improve biosecurity policies and to enhance our pandemic preparedness.

11. **HHS initiated debarment of the Wuhan Institute of Virology from receiving federal funding for the next ten years. However, according to the NIH website, over two dozen other animal labs in China, including many with ties to the Chinese Communist Party (CCP), are currently eligible for more taxpayer funding. Additionally, Government Accountability Office (GAO) audits in March and June of 2023 detailed problematic NIH loopholes that exempt labs in China and other foreign countries from oversight and transparency required of U.S. labs that receive taxpayer dollars. A recent review of federal spending identified millions of U.S. tax dollars still being sent to Chinese animal labs for virus experiments, including at several labs run by or tied to the CCP. Do you think the NIH should be sending tax dollars to labs in China?**
    a. **Do you think it makes sense for the NIH to exempt labs in China, Russia, and other foreign countries receiving taxpayer dollars from adhering to the same reporting, oversight and biosafety rules that govern domestic labs, especially ones handling dangerous pathogens?**

Response: NIH supports research to better understand the characteristics of animal viruses that have the potential to spill over to humans and cause widespread disease. We must collaborate with researchers in other countries where these sorts of viruses are prevalent because once a virus spreads to humans, it is not contained by geographical boundaries. The body of research on pathogens and infectious diseases is what has made it possible for the U.S. government to move so quickly to get a COVID-19 vaccine in an unprecedented timeframe. Countless lives have been saved as a result.

In addition, if confirmed as NIH Director, I will be committed to upholding all critical policies related to scientific review, monitoring and accountability, no matter the location of the research.

12. **Some of the boards overseeing NIH-funded clinical trials continue to mandate COVID-19 vaccination even though vaccination status is not germane to the research being conducted or the data being analyzed. Do you think it is ethically problematic for boards that are entrusted with overseeing clinical trials to mandate COVID-19 vaccination during study enrollment even when vaccination status is not relevant to the integrity of the data?**
    a. **Will you commit to ensuring that NIH funding recipients do not discriminate against unvaccinated candidates for participation in clinical trials?**

Response: NIH does not have a blanket policy requiring COVID vaccination for participation in clinical trials, but specific trials may have additional requirements that are set by the clinical trial sponsor based on the information that is being gathered for that particular trial.

13. **If confirmed, how will you ensure that congressional requests for information are answered promptly and in full, and how will you ensure that officials who failed to do so under your predecessors are held accountable?**

Response: I deeply respect the oversight function of Congress and its role in improving current policies and programs. I am committed to ensuring that NIH is appropriately responsive to congressional oversight requests consistent with constitutionally-mandated accommodation process.

14. Will you publicly commit to releasing all records requested by Members of Congress?

Response: I deeply respect the oversight function of Congress and its role in improving current policies and programs. I am committed to ensuring that NIH is appropriately responsive to congressional oversight requests consistent with the constitutionally-mandated accommodation process.

15. The next NIH Director will be tasked with leading the development of the agency-wide strategic plan for fiscal years 2026-2030. As you know, this is an important responsibility that sets out agency priorities for the next five years. During the previous strategic planning process, the NIH only gathered stakeholder input on a short, rough framework of the proposed strategic plan, preventing the public from providing feedback about specific language or programmatic details. In addition, it is unclear how that input was considered as the agency developed its final strategic plan. Given the tremendous amount of taxpayer money spent to fund the agency's work, the public is due the opportunity to comment on a full draft plan and transparency on how that feedback is incorporated into the final strategic plan. To ensure public accountability, how will you enhance transparency and opportunities for stakeholder input during the development of the upcoming NIH Strategic Plan?

Response: NIH is the steward of our nation's medical and behavioral research, and I am committed to ensuring that NIH continues to be a force of innovation and discovery. To do that, we need to rebuild trust in science and engage with the American people transparently and consistently in our efforts. I look forward to engaging with the broadest possible group to bring health solutions to the American people.

16. Is it reasonable for intramural NIH scientists to receive patent royalty payments for their taxpayer-funded research discoveries?

a. If you believe royalties are appropriate to attract top scientists to the NIH, can you explain how it helps science in this country if the NIH recruits the top scientists away from universities and other research institutions around the country?

Response: The Federal Technology Act of 1986 authorizes government agencies to license their inventions in exchange for royalties that the agency can use to fund further research. NIH typically receives annual minimum royalty payments and a percentage of the sales of the end-product. The law requires that NIH pay a portion of the royalties it receives to the inventors according to a statutory formula (15 U.S.C. 3710c) and the remainder to the NIH Institutes where the inventions were made. NIH-funded universities and research hospitals have similar programs governed by the Bayh-Dole Act of 1980 (35 U.S.C. 202(c)(7). Royalties to NIH also pay for the cost of obtaining patents. If confirmed as NIH director, I would ensure that all NIH policies are consistent with the law.

17. Many academic scientists receive funding from both the government and the pharmaceutical industry. Does this funding mechanism create a potential conflict of interest?

a. Should the NIH try to ensure that there are academic scientists who are independent of the pharmaceutical industry?

b. How can such scientific independence be accomplished?

Response: NIH requires the disclosure of all sources of research support, foreign components, and financial conflicts of interest for senior/key personnel on research applications and awards. NIH uses this information when making its funding decisions to determine if the research being proposed is receiving other sources of funding that could be duplicative, has the necessary time allocation, or if financial interests may affect objectivity in the conduct of the research. I am committed to ensuring proper stewardship of taxpayer dollars.

18. Should the NIH coordinate its research activities with pharmaceutical companies?

Response: The NIH funds primarily basic, translational, and early-stage clinical research and relies on partnerships with the private sector to bring discoveries to market. Coordination with private companies, like those in the pharmaceutical industry, can lead to accelerated innovation towards techniques and treatments that improve the health outcomes for people across the United States. I believe, however, that NIH must always ensure that companies do not unfairly profit from the investment that taxpayers have made into NIH for the public good, and that public investment yields public benefits. I look forward to working with you to ensure that NIH coordination with private industry remains a balanced partnership between the private sector and the American people.

19. Documents obtained by the independent watchdog group OpenTheBooks revealed that between 2009 and 2021, approximately 54,000 royalty payments totaling $325.8 million were paid by third party entities to NIH researchers credited as co-inventors. However, important information including the sources of the payments was redacted by the NIH. To avoid the appearance of conflicts of interest, will you commit to disclose publicly any royalty payments to NIH researchers by third parties, including the sources of those payments?

Response: If confirmed, I am committed to transparency, and ensuring that the NIH provides information to the public consistent with applicable law.

20. A bill I introduced, the FDA Modernization Act 2.0, which became law on December 29, 2022, amended the Federal Food, Drug, and Cosmetic Act to remove an outdated animal testing mandate and give drug sponsors the freedom to use modern alternatives to animal testing to assess the safety and effectiveness of new drugs. Unfortunately, despite the change in law, there have been several recent examples of expensive testing on dogs and other animals that were commissioned by the NIH and only canceled and determined to be unnecessary after criticism from Congress and independent watchdog groups. How would you improve the current review system to ensure the NIH does not spend taxpayer dollars wastefully on drug tests on animals that are no longer required by law?

Response: All animals used in NIH-funded research are protected by laws, regulations, and policies to ensure the smallest possible number of subjects and the greatest commitment to their welfare. This includes ensuring that harm and distress is minimized as much as possible. Domestic institutions receiving funds from the Public Health Service (PHS) must conduct research involving live vertebrate animals in accordance with the PHS Policy on the Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy requires all institutions to comply, as applicable, with the Animal Welfare Act and other Federal statutes and regulations relating to animals. Compliance with this Policy is a collaborative effort between the NIH, scientific investigators, and research institutions.

The NIH Office of Laboratory Animal Welfare (OLAW) provides oversight of compliance with the PHS Policy in all NIH-supported research that involves vertebrate animals. All institutions that conduct PHS funded research, testing, or training are responsible for ensuring animal welfare and are obligated to protect the federal investment in these activities. OLAW investigates allegations concerning animal welfare and appropriate animal care in NIH-funded studies. NIH-funded institutions must report promptly to OLAW any violation of the PHS Policy. OLAW considers these reports and requires the institution to make appropriate corrections and to prevent further violations.

If confirmed as NIH Director, I will work to ensure NIH continues to comply with all applicable laws and policies and continues to support the use of alternatives to animal testing, when appropriate.