



August 16, 2024

Dear United States House of Representatives,

On behalf of the American College of Emergency Physicians (ACEP) and the Society for Academic Emergency Medicine (SAEM) we would like to express our collective concerns regarding the proposed framework restructuring of the National Institutes of Health (NIH) Institutes and Centers (ICs).

The NIH has long been a transformative force for medical discovery, largely due to the foresight of Congress and the Executive Branch in creating this international gold standard for a federal research agency. While the stated goal of this reform is to, “position the NIH to better succeed moving forward,” there is no evidence this proposal will have the desired effect. Possible issues include excessive administrative complexity, the misalignment of funds with the needs of patients and scientists, and the likelihood of disruption to high quality science.

#### *Increased Administrative Complexity*

The proposed approach to "reducing silos" by consolidating agencies will likely lead to even greater administrative complexity and loss of focus for the ICs. For example, within the National Heart, Lung and Blood Institute (NHLBI), blood studies currently compete with lung studies and cardiology studies across multiple life stages. All these areas of inquiry deserve our research efforts, but grouping them together promotes inappropriate competition between unrelated topic areas. More narrowly defined ICs currently benefit from a more focused research agenda, but this benefit will be largely lost with this proposal. **The reorganization of ICs requires significant due diligence by an independent body.**

#### *Misalignment of Research Funds*

The proposed restructuring will likely exacerbate existing gaps in the distributive equity of funding across the healthcare landscape relative to the public health burden of disease. There are already many important medical conditions that do not have a natural research home at NIH, such as traumatic injury, sepsis, and violence, but this proposal will evict even more. Disruptively reshuffling the number and content of these silos without evidence of efficacy will only serve to de-emphasize the translation of needed science to clinical care if the proposed ICs are not structured in a way that is compatible with how research is conducted and healthcare is actually delivered. Individual ICs should be at the center of determining research priorities and establishing long term plans for translation to clinical settings, but they need input from clinicians and scientists to do that. If the NIH is to be restructured, clinicians and scientists should play a role in that as well. **In short, these new categorizations as proposed will only create larger gaps between what NIH funds and what ultimately helps patients and improves the health of the US population.**

#### *Disruption to High Quality Science*

The proposed changes will also disrupt ongoing high-quality science. Logistical changes such as capping facilities and administrative (F&A) and indirect costs, limiting grant awards and enacting term limits may have unforeseen effects and require due diligence in assessing their implications. Established institutes and centers have been effectively overseeing and conducting world class research for decades in their current forms. Rather than arbitrarily changing the structure of the ICs to accommodate the opinions of a few, a more measured approach with meaningful engagement of the scientific community and careful consideration of the potential outcomes of these changes would be more conducive to future success. The priorities in this reorganization should be maintaining scientific rigor and pursuing the most promising avenues of scientific inquiry, and this demands a systematic approach. In the past, Congress has made rapid but well-meaning changes in the scientific realm that ended up causing harm. For example, the FDA

accelerated approvals program was intended to push new and promising drugs to market faster, but more than half of those drugs were ultimately withdrawn from the market.<sup>1</sup> **As described, the proposed restructuring also has the potential to be extremely disruptive and to set back our national biomedical research mission by decades.**

#### *Recommendation*

If Congress is willing to undertake NIH reform, a much more comprehensive approach should be taken to develop a plan that engages the scientific community and focuses resources on the leading causes of death and disability as well as health care expenditures in the United States. If this is desired, ACEP and SAEM jointly recommend that Congress engage the services of an independent medical body, such as the National Academy of Medicine, to conduct a review of the NIH infrastructure and to issue recommendations for structural reform.

#### References

1. Wosen J. About half of cancer drugs given accelerated approval don't show improved survival or quality of life. STAT. Published April 7, 2024. Accessed August 7, 2024. <https://www.statnews.com/2024/04/07/cancer-drugs-accelerated-approval-aacr/>