

Representing Over 110,000 Researchers

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August 6, 2024

The Honorable Diana DeGette 2111 Rayburn House Office Building Washington, DC 20515 The Honorable Larry Bucshon, MD 2313 Rayburn House Office Building Washington, DC 20515

RE: Request for Information on Next-Generation Cures Bill

Submitted via e-mail: cures.rfi@mail.house.gov.

Dear Representatives DeGette and Bucshon,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Request for Information (RFI) regarding future legislation needed to advance science and develop treatments for patients. As a coalition of 22 member societies representing over 110,000 researchers across a broad range of scientific disciplines, we affirm the critical role of biomedical research and scientific innovation in achieving this goal.

The 21st Century Cures Act had significant impact on the National Institutes of Health (NIH)'s ability to remain at the forefront of biomedical research. This research serves as the foundation for investigating biological processes and understanding mechanisms underlying the nation's most devastating diseases. We are grateful for Congress' efforts to ensure that the biomedical research enterprise is well-positioned to drive the next wave of innovative breakthroughs while supporting the future generation of researchers.

Nevertheless, FASEB recognizes that NIH faces key challenges that prevent the agency from maximizing the full breadth of current and future scientific opportunities. Our comments focus on the third question of the RFI related to additional reforms, support mechanisms, or incentives needed to improve the effectiveness of progress made thus far. Specifically, NIH could benefit from additional reforms in the following areas:

- 1. Stable funding and operational support
- 2. Supporting the biomedical research workforce
- 3. Improving the diversity of the biomedical research workforce
- 4. Promoting data management and sharing
- 5. Reducing regulatory burden in biomedical research

Stable Funding and Operational Support

Robust and consistent funding for NIH is essential for advancing biomedical research and promoting the next generation of treatments and cures. FASEB appreciates the opportunity to share feedback on this topic, though we recognize the House Energy and Commerce Committee leadership's *Reform for the NIH Framework for Discussion*—another RFI with similar themes and implications for NIH—is already

partially integrated into the Fiscal Year (FY) 2025 Labor, Health and Humans Services and Education and Related Agencies bill approved by the House Appropriations Committee. Before enacting major reforms at NIH, FASEB urges Congress to solicit to stakeholder feedback and conduct comprehensive hearings on suggested structural and operational changes, including the consolidation of existing institutes and centers, to prevent potential changes from causing unintended consequences that could negatively affect the biomedical enterprise.

To achieve stable and predictable funding for the agency that can sustain critical infrastructure and support the research workforce, FASEB recommends ensuring the base budget keeps pace with the Biomedical Research and Development Price Index (BRDPI) plus five percent. Adopting a funding strategy that allows for real growth enables NIH to address emerging research priorities and helps investigators plan projects effectively. In congressional testimony, former NIH Director Francis Collins also called for "a stable trajectory of inflation plus five percent for multiple years in a row" to optimally support the medical research enterprise in advancing discovery and improving health. Furthermore, using the BRDPI index plus five percent is consistent with prior bills related to biomedical research, including, the American Cures Act in 2014, which acknowledges that even flat funding creates challenges for the biomedical research enterprise.

Secondly, FASEB supports reauthorizing the NIH Innovation Fund, first established by the original Cures legislation, but encourages broadening the focus of this fund to support scientific opportunities subject to the existing peer review process. While we recognize the importance of the four research areas supported through the Innovation Fund (All of Us Research Program, BRAIN Initiative, Cancer Moonshot, and the Regenerative Medicine Innovation Project), a broader scope will allow NIH to successfully and readily adapt to its evolving needs and priorities. For example, FASEB recommends using the Innovation Fund to support early-career investigators, aiding NIH in driving science forward and nurturing the next generation of researchers. Together, this approach and flexibility enable the Innovation Fund to serve as a vehicle that can connect scientific ideas with effective implementation.

FASEB greatly appreciates the bipartisan support for NIH over the last decade. From 2015 to 2023, Congress increased NIH's budget by 60 percent, or by \$18 billion. In addition to enhancing our ability to address important biomedical research questions, such support has had a profound effect on the economy. For instance, NIH generated nearly \$97 billion in economic activity in 2022 alone. However, in FY 2024, Congress only provided a meager two percent increase to NIH's funding—barely keeping pace with inflation. This is at a time when critical technologies and the scientific workforce need to be strongly supported to keep the U.S. globally competitive and ensure our talent and infrastructure can effectively address future public health challenges.

Supporting the Biomedical Research Workforce

As previously mentioned, FASEB strongly recommends future Cures legislation include dedicated, robust support for the research workforce, particularly early-career investigators. Areas that warrant specific focus and are further described below include bolstering support for postdoctoral researchers, fostering the growth of international scholars, establishing additional funding mechanisms for early-career investigators, and strengthening data collection efforts on trainees.

Postdoctoral Scholars

FASEB strongly supports the postdoctoral research workforce and believes NIH is well-positioned to create positive changes that enhance the postdoctoral training ecosystem. This can be achieved, in part, by implementing recent recommendations from the Advisory Committee to the Director (ACD) Working Group on Re-envisioning NIH-Supported Postdoctoral Training. Postdoctoral scholars often receive low compensation and benefits relative to their education and experience. They experience job insecurity, insufficient professional development support, and uncertain career prospects, while also encountering power imbalances that favor the institutional establishment. Echoing our prior comments in response to the ACD working group RFI, FASEB reaffirms that postdoctoral positions should be short-term, well-defined, and lead to independence in the chosen career. Additionally, we encourage Congress to urge NIH to find creative solutions that ensure all postdoctoral scholars, regardless of pay mechanism, have access to standard employee benefits.

FASEB applauds NIH for accepting the recommendations put forth by the working group and, more recently, increasing pay levels for pre- and postdoctoral scholars at grantee institutions. While not the full funding increase recommended by the working group, we support the agency's commitment to further increase stipend levels over the next three to five years and encourage equal attention toward implementing the remaining recommendations. Opportunities we are particularly excited about include expanding and revising K99/R00 mechanisms to better support the diverse talent pool of postdoctoral scholars, providing resources for international postdocs related to visas and immigration, and empowering diverse perspectives to foster safe research environments free from harassment.

To ensure effective implementation, FASEB strongly recommends leveraging the full spectrum of talent and viewpoints of the biomedical research community. Scientific societies, including FASEB, and academic institutions are key players that can facilitate NIH's goals in improving the experience of postdoctoral scholars. As staunch supporters of a diverse workforce, we welcome opportunities to collaborate on this important topic and hope that NIH will be encouraged to continue working with stakeholders to diversify the biomedical research workforce.

International Biomedical Research Workforce

To recruit and retain a strong, diverse biomedical research workforce, FASEB recommends NIH be given the authority to create and expand support mechanisms for international graduate and postdoctoral scholars. The U.S. research workforce relies on a diverse population of graduate students and postdoctoral scholars, including international researchers who comprise a significant portion and are essential to U.S. research excellence, economic growth, and national security. According to the 2022 National Science Foundation (NSF) <u>Survey of Earned Doctorates</u>, 34.1 percent of doctoral students hold temporary visas. Additionally, the 2021 Federally Funded Research and Development Centers <u>Survey of Postdocs</u> revealed that 51.1 percent of all postdocs held temporary visas. NSF's data indicate that the U.S. relies on international doctorate recipients to fill critical science and technology jobs, and a recent National Science Board <u>policy brief</u> also highlights the importance of attracting and retaining global talent while strengthening our domestic biomedical research workforce.

FASEB affirms international scholars as vital members of the U.S. research enterprise and recognizes the unique challenges these scholars face due to their international status. As previously stated in our

<u>comments</u> to the ACD postdoc RFI, FASEB recommends NIH provide stability to postdoctoral positions through contract extensions because one-year contracts create unnecessary hurdles, especially for postdocs on temporary visas. Additionally, we encourage Congress to allow NIH to establish dedicated funding opportunities for international postdocs where legally and programmatically possible.

FASEB has previously noted the barriers international scholars face across U.S. immigration and citizenship (USCIS) benefits and services and expressed concerns about the additional burdens imposed upon them. Over three-fourths of noncitizen recipients of STEM doctorates choose to stay in the U.S. for subsequent employment. International students receive F-1 (student) and J-1 (exchange visitor) visas, while many non-citizen professionals are selected by firms primarily through H-1B temporary visas. Consequently, USCIS policies significantly impact employers' access to this crucial source of STEM talent. Such burdens threaten the nation's competitiveness by discouraging future scientists from pursuing educational programs in the U.S. and conducting cutting-edge research vital for biomedical progress.

To address this, FASEB urges NIH to consider the unique needs of international scholars, ensuring they are supported and able to continue their scientific contributions. One potential way to achieve this could be partnering with USCIS to provide resources for navigating complex immigration policies. Additionally, we encourage efforts that would permit NIH to create and widely disseminate a training module for immigration education, with resources aimed at international scholars, their mentors, and institutional offices. These initiatives will lower barriers for temporary visa holders pursuing education and research opportunities in the U.S.

Establish Additional Funding Mechanisms for Early-Career Investigators

FASEB encourages Congress to give NIH the authority to establish additional funding mechanisms dedicated to early-career investigators that prioritize flexibility and research independence. These investigators experience intense competition for funding, which creates various challenges when beginning and sustaining an independent research career. As noted in our previous comments, FASEB strongly supports NIH's goal to develop programs and funding mechanisms for early-career investigators, particularly those that enhance career development and foster a diverse, inclusive, and representative biomedical research workforce. The Stephen I. Katz Early Investigator Research Project Grant Program and Maximizing Investigators' Research Award are excellent examples of providing flexibility for early-career investigators to pursue new research directions with stability and support for transitioning to independent careers. Moreover, these mechanisms offer distinct advantages for new investigators, such as longer award length and a strict prohibition on submitting preliminary data. Additional funding mechanisms with similar features can reinforce support for early-career investigators at a critical point in their careers, thereby enhancing scientific productivity and the potential for important breakthroughs.

Strengthening Data Collection Efforts on Trainees

While we greatly appreciate the publicly accessible data NSF collects on trainees, including sources of financial support, traineeships, fellowships, and grant dollars, comparable data from NIH is lacking. FASEB recognizes that the Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER) module provides data on trainees supported by training grants and fellowships. However, the majority of graduate students and postdoctoral scientists are supported by NIH research grant dollars, making them effectively invisible in RePORTER. There is also no robust data on postdocs paid from

grants, specifically regarding the national landscape of postdoc salaries when not on fellowship and any clear disparities for vulnerable populations.

FASEB concurs with the findings of the ACD Working Group on Re-envisioning NIH-Supported Postdoctoral Training final report which highlighted the need for NIH to collaborate with NSF and NCSES on data collection, analysis, and dissemination efforts. NIH could also consider partnering with institutions to monitor and report career outcomes for graduate students and postdoctoral scholars, ensuring this data is publicly available.

Improving the Diversity of the Biomedical Research Workforce

A diverse biomedical research workforce is central to maintaining our global leadership in science and technology. While various NIH programs have made significant progress toward enhancing diversity, additional work remains to achieve a diverse and inclusive workforce with equitable opportunities for all. FASEB recommends strengthening support in the following areas: mentorship, safe and inclusive research environments, recruitment, hiring, and retention, and caregiver support.

Mentorship

Mentorship is important for trainees in the biomedical workforce. FASEB recommends NIH update the criteria for trainee fellowships to reflect the importance of a mentoring network, rather than relying on the principal investigator (PI) to be responsible for the majority of training. Eliminating the expectation of a dyadic mentorship structure would fundamentally shift the focus from the PI to the scientific merit of the proposed project.

Furthermore, additional mentors to fulfill the professional development needs of the trainee beyond the sponsor(s) should be a scored criterion. The current emphasis on the sponsor does not create an expectation of trainees sustaining a meaningful mentor network. Scoring the sponsors' ability to mentor individuals should reflect the effort to utilize evidence-based mentoring practices. Such practices are not correlated to the length of time as a PI, as many junior PIs voluntarily undergo mentor training to improve their skills and there are senior PIs who do little to mentor students.

Finally, NIH can create new programs to model the benefits of sponsorship in addition to mentorship. Sponsors use their power and influence to publicly promote the careers of their proteges. Individuals from historically excluded groups may need a sponsor, in addition to mentors, to progress their careers. While traditionally utilized in the business sector, sponsorship is being incorporated in science. For example, there are a number of sponsorship programs in academic medicine, such as Drexel University's Executive Leadership in Academic Medicine program intended to develop the professional skills and careers of women faculty. A similar NIH-funded formal sponsorship program may help increase diversity in positions of power.

Safe and Inclusive Research Environments

Unsafe research environments—due to harassment, bullying, retaliation, or other hostile working conditions—are a driving factor for historically excluded populations leaving science. FASEB remains committed to addressing this issue and appreciates the work of NIH and other organizations in working to develop safer, more inclusive research environments. We encourage NIH to build on this progress by

employing promising practices collated by NSF and the National Academies for Sciences, Engineering, and Medicine (NASEM) through the Action Collaborative on Preventing Sexual Harassment in Higher Education (Action Collaborative) as part of their continued efforts to implement evidence-based practices that have shown success elsewhere.

Recognizing that NIH has taken several critical steps towards this goal already, one key topic highlighted by the Action Collaborative that FASEB strongly supports pertains to strengthening policies and enforcement to prevent "passing the harasser" in higher education. A recent <u>issue paper</u> by the Action Collaborative spotlights how two institutions—the University of California, Davis and the University of Wisconsin system—developed and implemented policies aimed at preventing the hiring of faculty who have a history of misconduct. Although some policies are specifically focused on sexual misconduct, they serve as helpful examples for addressing other harmful experiences individuals face in research environments, especially for those from historically excluded backgrounds.

Finally, FASEB suggests NIH coordinate agency programs and initiatives with ongoing community efforts, such as those spearheaded by the Societies Consortium on Sexual Harassment in STEMM. As a proud inaugural member of the consortium, FASEB has been working with other professional societies to establish uniform standards of excellence in STEMM fields, including professional conduct; model policies and implementation tools to cultivate inclusive environments are highlighted in the <u>Societies Consortium library</u>. By collaborating with such groups, NIH can increase awareness of existing resources to foster safe and inclusive research environments.

Recruitment, Hiring, and Retention

FASEB applauds NIH for its efforts to recruit diverse individuals in the biomedical workforce thus far. For example, the newly developed <u>funding opportunity</u> to solicit applications from institutions to conduct institutional climate assessments and develop action plans for the recruitment, hiring, retention, and advancement of faculty is an important step in achieving institutional culture change and enhancing the representation of historically excluded populations in the biomedical research workforce. FASEB urges NIH to take similar steps *within* the agency to ensure individuals from historically excluded groups are promoted into positions of meaningful leadership and power at all levels. Moving forward, it is important for NIH to evaluate past efforts to enhance diversity, pivoting away from initiatives that had little or no impact and building upon programs that have shown success.

Echoing our previous comments, FASEB also encourages NIH to enhance engagement with academic institutions, professional societies, and racial equity organizations to foster the development and retention of a diverse workforce. Numerous institutions, such as Historically Black Colleges and Universities, Hispanic-Serving Institutions, and Tribal Colleges and Universities, have demonstrated their commitment to educating students from historically excluded backgrounds and could serve as valuable partners in NIH efforts, including its recently established initiative on Engagement and Access for Research-Active Institutions. Collaborations with professional societies and racial equity organizations could also help inform the development of new programs toward this goal, as many discipline-specific societies have committees devoted to diversity, equity, and inclusion.

Finally, improved data collection can be another effective strategy for strengthening the recruitment and retention of a diverse biomedical workforce. FASEB recommends increasing granularity in demographic categories is needed to ensure existing barriers in the margins of intersectional experiences and identities of race, ethnicity, and gender are adequately addressed. NIH should align with measures like those taken by NSF data collection efforts which recently added questions about sexual orientation and gender identity to its Survey of Earned Doctorates.

Support for Caregivers

Caregiving responsibilities also pose unique challenges to recruitment and retention efforts; 43 percent of women and 23 percent of men who are new parents leave full-time STEM employment after their first child. The COVID-19 pandemic exacerbated these stressors. Ensuring caregivers are not pushed out of the workforce is crucial. Therefore, FASEB encourages NIH to prioritize flexibility for grant recipients with caregiving responsibilities when developing or modifying policies. One feasible strategy to achieve this goal involves providing research supplements to promote reentry for individuals following caregiving leave. Other flexibilities that would have considerable influence on this important demographic include no-cost extensions based on caregiving needs and flexibility in eligibility timelines. These recommendations are consistent with conclusions highlighted in the recent NASEM consensus study, "Supporting Family Caregivers in STEMM: A Call to Action."

FASEB applauds NIH's recent decision to increase the childcare subsidy by an additional \$500 for over 17,000 early career scholars supported by NIH Kirschstein National Research Service Awards, from \$2500 to \$3000 for FY24. Building on this decision and using existing research findings, we encourage NIH to develop and offer caregiver policy guidance to the institutions they fund, to support the retention, re-entry, and advancement of biomedical professionals with family caregiving responsibilities. Similarly, FASEB supports developing policy accommodations such as parental leave and affordable on-site childcare to ensure researchers with caregiving responsibilities feel supported and welcomed.

Promoting Data Management and Sharing

In 2013, the White House Office of Science and Technology Policy (OSTP) issued *Increasing Access to the Results of Federally Funded Scientific Research*, a memorandum that directed Federal agencies with over \$100 million in annual research and development expenditures to develop plans to facilitate public access to the results of research funded by the federal government. Section 4 of the memorandum – "Objectives for Public Access to Scientific Data in Digital Formats" – required that all extramural researchers receiving federal funds for scientific research develop data management plans describing the long-term preservation and access to scientific data resulting from federally funded research. Recognizing that there are costs associated with data curation, preservation, and access, the memorandum also allows for the inclusion of appropriate costs associated with data management and sharing in proposals for federal funds.

Although NIH established a <u>data sharing policy in 2003</u>, it was relatively limited in scope. Work on an updated policy to meet the parameters of the 2013 OSTP memorandum began in earnest in 2018, with the <u>final policy</u> published in October of 2020. Throughout this process, FASEB was actively engaged in providing feedback on the updated policy, specifically highlighting the need for financial resources to

ensure meaningful implementation and enforcement of the expanded data management and sharing requirements. However, the first year of the policy's implementation highlighted a critical need for resources – both within NIH and the extramural research community – to ensure uniform understanding and enforcement of the policy.

The release of a <u>second OSTP memorandum</u> in August 2022 that expands upon the goals of the 2013 memo to ensure free, immediate, and equitable access to federally funded research highlights the need for the authorization of additional funds to support implementation of the 2023 NIH Data Management and Sharing Policy (DMSP). Recommended tactics include:

- Designated funding to support collection of data to understand resources required by institutions
 to support researchers' development and implementation of the NIH DMSP, including access to
 data curation resources and costs associated deposition into an appropriate repository;
- Establishment of Notices of Funding Opportunity to encourage the development of resources including workshops and training materials to support individual researchers in generating and implementing data management and sharing plans in compliance with the NIH DMSP; and
- Authorization of funds to support a prize competition to promote and celebrate best practices in data management and sharing to advance scientific discovery. As an example, Since 2022, FASEB has partnered with NIH's Office of Data Science Strategy to offer the DataWorks! Prize a competition to reward research teams for adopting novel strategies to integrate data sharing and reuse to advance scientific knowledge through the challenge mechanism authorized by the 21st Century Cures Act and the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Reauthorization Act of 2010. The first two iterations of the DataWorks! Prize engaged over 1,000 individual scientists, with winning entries highlighting the importance of data collection, curation, sharing, and reuse to further our understanding of human health and disease.

There were a lot of lessons learned during the first year of implementation of the NIH DMSP, many of which resulted in key clarifications for applicants (e.g., NOT-OD-23-161, NIH Application Instruction Updates – Data Management and Sharing (DMS) Costs) but also many questions that risk relegating the policy to one of compliance over long-term utility of federally funded science. Therefore, in addition to authorizing funds designated towards effective implementation of the NIH DMSP, FASEB recommends the following strategies to ensure the policy not only fulfills the expectations of OSTP directives but reflects the state of the science and available resources while fostering culture change:

- Continuous review of feedback from individual NIH Institute and Center (I/C) program officers on the quality of information contained within data management and sharing plans to identify recurring gaps that may require additional clarification, appendices, or amendment to the original policy; and
- Development and application of metrics to assess the effectiveness of the policy to promote behavior change related to data sharing and reuse. While some <u>models</u> exist, demonstrating that the policy is achieving desired outcomes will promote a culture in which data sharing and reuse is the norm rather than the exception.

Reducing Regulatory Burden in Biomedical Research

One of the central tenets of the original Cures Act emphasized reducing administrative burden for researchers and institutions. FASEB recognizes this is a monumental endeavor and appreciates the work completed thus far, though significant challenges remain. Our comments focus on alleviating the administrative burden associated with animal research and extending broader agency exemptions and flexibilities to facilitate improved research efficiency.

Animal Research Regulations

FASEB affirms the critical role of humane animal research in sustaining biomedical research progress. However, the exponential increase in administrative work over the past decade has resulted in increased costs and reduced research productivity, jeopardizing long-term national interests in science and medicine. Although the policy changes and updated resources resulting from the NIH's 2019 report represent substantial steps forward in addressing inconsistent and overlapping regulations, several topics highlighted in the report remain unresolved. Federal agencies originally anticipated implementing policy changes within a two-year timeframe (pg. 8, 2019 report). Unfortunately, this prolonged implementation timeline further magnifies the challenges, inefficiencies, and general burden that investigators and Institutional Animal Care and Use Committees (IACUCs) currently experience because of conflicting policies.

A major source of administrative burden in animal research studies is grant-to-protocol congruence review. While FASEB appreciates NIH's updated guidance (NOT-OD-22-005), the guidance serves as a clarification notice rather than policy changes that could streamline this cumbersome process. As noted in previous comments, FASEB recommends aligning IACUC protocol reviews with NIH grant length. The current timing discrepancy between protocol reviews (e.g., three years) and the average length of NIH grants (e.g., four or five years) causes unnecessary research delays and interruptions in animal care. This is because investigators are compelled to keep animals in a holding pattern while experiments are postponed or suspended until protocol reviews are complete. Examples like this demonstrate that while the various federal requirements are intended to enhance accountability, many of these tasks do not promote animal welfare or improve research quality.

Another area causing increased regulatory burden for researchers and IACUCs is related to reporting IACUC-approved departures from the *Guide for the Care and Use of Laboratory Animals (Guide)*. Given the *Guide*'s definition of "should" which permits alternative strategies with justification, FASEB encourages Congress to allow NIH to amend the Public Health Service Policy and no longer consider deviations from "should" statements as reportable items. This requirement is redundant and undermines the legislative authority provided to IACUCs through the Health Research Extension Act of 1985, significantly increasing institutional burden with little evidence to suggest it improves animal welfare. Modifying this policy will greatly improve institutional flexibility and administrative burden levels, a crucial goal of the original Cures bill

Extending NIH Exemptions and Flexibilities

Finally, FASEB recommends Congress extend two crucial exemptions and flexibilities afforded to NIH through the Cures Act that enable the agency to launch research projects faster, generate new scientific knowledge, and strengthen outreach efforts with the biomedical research community. The first is eliminating the Paperwork Reduction Act requirements for NIH research. The information collection

approval process typically takes around nine months to complete and rarely leads to significant changes, often preventing researchers—particularly early-career investigators—from pursuing crucial studies.

Additionally, we strongly encourage Congress to continue lifting travel restrictions associated with scientific meetings for NIH staff and allow federal employees to freely travel to outside conferences. Previous travel restrictions prohibited scientific collaboration and resulted in unnecessary paperwork and extra costs for NIH. Permitting staff to present scientific ideas, establish collaborations, and enhance their professional development at scientific conferences is consistent with Congress' longstanding goal to advance biomedical research, strengthen its workforce, and develop new treatments for patients.

Conclusion

FASEB appreciates the opportunity to provide our expertise as Congress looks to further the original Cures law and considers ways to optimize NIH operations. Our recommendations related to stable funding, supporting the biomedical research workforce, improving the diversity of the biomedical research workforce, promoting data management and sharing, and reducing regulatory burden in biomedical research could significantly improve the biomedical enterprise and better prepare us for the future.

Please do not hesitate to contact us should you have any questions related to our feedback. Our point of contact is Ellen Kuo, Associate Director of Legislative Affairs at ekuo@faseb.org.

Sincerely,

Beth Garvy, PhD FASEB President

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