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Office of Science Policy
National Institutes of Health
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To whom it may concern,

The Infectious Diseases Society of America (IDSA) is writing to share feedback on the proposed changes to the National Institutes of Health's (NIH's) policies regarding allowable publication costs. IDSA represents over 13,000 infectious diseases (ID) physicians and researchers, many of whom are directly impacted by these policies. Within IDSA, the HIV Medicine Association (HIVMA) represents nearly 6,000 HIV clinicians and researchers working on the front lines of the HIV epidemic. In addition, IDSA's and HIVMA's journals publish practice-changing clinical research that clinicians can use when caring for patients; bench-to-bedside or bedside-to-bench translational infectious diseases science; and research fostering collaboration among practitioners, researchers and policymakers, to improve public health outcomes. We are committed to ensuring that any policy changes do not diminish the ability of scientists and researchers to continue publishing high-quality clinical and laboratory research for the benefit of all Americans.

IDSA and HIVMA understand and share NIH's commitment to responsible publication of federally funded scientific research. Modifications to NIH's publication policy will have a dramatic impact on the entire scientific publication industry, and research overall. We agree that there are aspects of the research publication process that can and should be changed, but stress that any viable solution must meet the needs of both journals and researchers. We especially reiterate the need for policies that ensure that researchers are able to freely publish in journals of their choice, without funding limitations. We have highlighted the areas below for consideration as NIH makes modifications to its publication costs policies.

Preserving the strength of scientific journals is fundamental to improving human health. Federally funded research that has gone through peer review and been published in journals is critical to inform medical practice, improve patient outcomes and save lives. These examples demonstrate the critical importance of maintaining NIH support for peer-reviewed scientific publication:

- **Dorman, Susan E., Nahid, Payam, et al. (2021), "Four-Month Rifapentine Regimens With or Without Moxifloxacin for Tuberculosis," *New England Journal of Medicine.*** This article showed that the efficacy of a four-month rifapentine-based regimen containing moxifloxacin was noninferior to the standard six-month regimen in the treatment of tuberculosis. The research published here helped shorten treatment times for TB, improving patients' lives and reducing health care costs. **Funded by CDC.**

- **Cohen, Myron S., Chen, Ying Q., et al. (2011), "Prevention of HIV-1 Infection With Early Antiretroviral Therapy," *New England Journal of Medicine*.** This article demonstrated the effectiveness of antiretroviral therapy that reduces viral replication could limit the transmission of human immunodeficiency virus type 1 (HIV-1) in serodiscordant couples. This publication led to tremendous gains in preventing HIV transmission and helped launch the Undetectable = Untransmittable campaign. **Funded by NIH.**

These articles are a small sampling of the many published pieces that have improved patient care and saved lives. Without journals to publish and disseminate these critical pieces, medical advancement would lack the foundation of widely available, evidence-based work to inform the progression of care; medical progress would stagnate; and patients would suffer needlessly.

Many of the options given in the RFI would cause publication prices to increase, which would limit the accessibility, reproducibility and impact of research. This would unduly limit researchers' ability to publish. In most cases, these options do not accurately reflect the cost per article in journal publication and would limit researchers' abilities to publish. For selective journals such as ours, the pricing for individual published articles is based on the costs involved in supporting peer review as well as publication integrity and other quality assurance efforts for both a small number of accepted articles and a much larger number of rejected articles (which still must be reviewed and checked for possible integrity or quality issues). The pricing also reflects the cost of the supporting infrastructure required to copyedit and typeset papers as well as host content online, develop appropriate metadata to ensure its discoverability and utility, archive it with digital preservation services, downstream it to all appropriate indexing services in a timely and accurate way, deposit content in archives such as PubMedCentral and ensure its security against bad actors. In this time of rapid technological change, publishers must also work constantly to maintain their digital platforms and update them in response to new developments such as agentic AI.

Out of the options given for a revised publication policy**, option four, which sets a limit on the total amount of an award that can be spent on publication costs, would be the least problematic for ID research.** While we would strongly stress that none of the provided options are optimal, we believe this option best supports the researcher's freedom to publish in the journal best suited to their research and ensures journals can maintain an adequate level of peer review as well as publication integrity and other measures to ensure the quality and reliability of published research. Setting a percentage limit on publication costs is more inclusive of factors like inflation and increase in overall research costs over time. If NIH proceeds with this policy, the agency should monitor implementation and impacts of the change. If inflation and increased costs are limiting factors, NIH should adjust the percentage to ensure researchers maintain that freedom of publication. We also agree that this option would not disproportionately impact smaller awards, which should be a priority of the final policy. We would also stress the point made in the RFI that "NIH may consider exemptions to the cap with agency approval for unusual, high-volume publication situations"; any policy on publication costs must be flexible and should consider how widely utilized many NIH publications are. Individual researchers must be able to freely choose what type of journal is best for their publication and should have the resources to pursue the right choice for their work. It is also important to avoid unintentionally

driving researchers to lower-quality, but less expensive, publications that lack the quality control, publication integrity standards and visibility that NIH-funded research deserves.

IDSA and HIVMA are concerned that the other options in the RFI would burden researchers. **If the burden of publishing NIH-funded research increases, young scientists will have much more difficult time publishing research.** Knowing that their ability to publish will be limited will dissuade many students from pursuing careers in research, diminishing our already inadequate pipeline of scientists. The ID research workforce is already incredibly limited due to the cost of completing additional research training and a lack of federal investment into early-career ID research grants. Many ID fellowships are unable to fill their slots in the annual match, and the number of ID physician-scientists has plateaued at many institutions. Further limiting early-career researchers' ability to publish will further limit the amount of ID physician-scientists able to enter and remain in the research pipeline. Further, many researchers will have to make up funding elsewhere if NIH drastically limits publication costs, often by reducing staff in labs and on research teams — disproportionately impacting students and early-career researchers, who will likely be the first to be cut. IDSA and HIVMA have already heard reports of this occurring in infectious diseases labs, and this would only increase if a hardline approach to publication fees goes into effect.

Further, these policies would be detrimental to journals and limit their ability to have robust peer review processes. Journals provide an essential scientific process with peer review, and standards for this process are internationally regulated to ensure only evidence-based work is published in reputable journals. The International Committee of Medical Journal Editors, World Association of Medical Editors and Committee on Publication Ethics all provide strong standards for peer review that ensure high-quality research without conflicts of interest is published. As previously stated, most of the options given in the RFI would cause publication prices to increase. Many journals rely on author fees to pay for staff to handle logistics and operations of the journal. If NIH support for publication fees is extremely limited, scientists will submit fewer articles based on NIH-funded research. This has two negative effects: First, we lose opportunities to learn from and build on scientific work supported by NIH. Second, journals receiving fewer submissions may need to accept a higher percentage of those submissions they do receive — in some cases, those with less robust research — to ensure their continued viability. We are also concerned that more stringent publication fee policies would further consolidate the journals market among a small group of very large publishers, as smaller publishers would have a more difficult time remaining financially viable. The more publishers consolidate, the more power over publishing rests in a small number of companies, decreasing competition and increasing those publishers' ability to set pricing and policy that will impact all scientists.

The loss of robust peer review would be extremely detrimental to the overall quality of research. **Reproducibility of research would be very limited. If researchers must be more selective about what they publish due to less funding, they will likely choose to publish novel work that better advances their careers and that increases their ability to secure further funding, rather than replication studies**. While novel research is important, we agree with NIH that reproducibility in scientific research is critical and must be supported to ensure high-quality, evidence-based science. Ensuring a flexible, supportive publication fee policy would allow researchers to reproduce, and then publish that reproduced research.

Further, the widespread publication of research provides a huge benefit to the American public. Taxpayer dollars should support high-quality science. Rigorous peer review provided by journals is a chief mechanism to ensure that quality. Journals provide an access point for all science in an accessible, time-lined format. In case of corrections and retractions, journals also provide a reliable version of record that researchers can trust to reflect the latest information on that publication, while also down-streaming correction and retraction statements to vital indexes such as PubMed that scientists use daily in their work. Journals also ensure that research is included in digital preservation archives, so that even if the journal ceases publication, research published through that journal remains accessible in perpetuity. A lack of reliable, accessible, peer-reviewed work will impact the overall effectiveness of research, medical care and public health. Public health practices require evidence-backed research; without this, they will be less effective for the American people and will make Americans more vulnerable to biosecurity threats. This approach would also leave the country vulnerable to dual-use research-of-concern threats that may not undergo proper review. In a journal environment, editors can ensure that authors include context and potential concerns about misuse in their papers, or commission commentaries to accompany a paper and provide that needed context.

IDSA and HIVMA recognize the importance of ensuring taxpayer money is being used responsibly and spent on facets of research that directly benefit the American people. As outlined above, we believe publication of NIH research represents a huge benefit to the American taxpayer and advances American science. We would urge NIH to appropriately consult the research community and academic journals to ensure a new publication fees policy would meet the needs of the entire research ecosystem. We hope our comments will be useful in NIH's efforts to ensure their researchers are able to publish research that advances American science. If you have questions about these comments or if we can help inform your efforts, please contact Eli Briggs, director of public policy, at ebriggs@idsociety.org.

Sincerely,

Tina Q. Tan MD

Tina Tan, MD, FIDSA, FPIDS, FAAP
President, IDSA

Colleen Kelley

Colleen Kelley, MD, MPH, FIDSA
Chair, HIVMA