January 6, 2023

Lawrence A. Tabak, D.D.S., Ph.D.
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Tabak,

We, the undersigned organizations, representing biomedical societies and clinical journals that support and disseminate science, share the goals of the White House and its Office of Science and Technology Policy (OSTP) of facilitating access to taxpayer funded research. Together we publish over 8,000 articles a year and represent over 300,000 US based members. We represent the most highly rated, highest impact journals in our respective fields.

We are concerned that implementation of the OSTP guidance without fuller consideration and understanding of the science communication ecosystem could undermine the Administration's stated objectives. Seeking to help avoid this unintended consequence, the signers of this letter have collectively discussed the opportunities and challenges that a forthcoming policy from the NIH might have on our programs and our members. With this letter, we request a meeting to share and discuss the unique considerations of our journals.

There are many valuable activities that not-for-profit societies fund through journal revenue that is potentially at risk with new public access policies—to include supporting the research efforts of our members, advocating on behalf of increased funding for the NIH and its Institutes, and broad educational efforts that advance patient care.

In particular, clinical journals have an important role in maintaining high quality in medical research. In addition to supporting review activities that ensure articles are accurate, reproducible, and unbiased, many of our journals have policies that:

- Encourage or require data sharing,
- Require that trials be registered,
- Require approvals and adherence to CONSORT and other reporting standards,
- Aid in reproducibility of results,
- Require or encourage investigators to report on the racial and gender breakdowns of clinical trial participants or research subjects, and
- Maintain databases and tools that collect and report financial disclosures of our contributors to ensure maximum transparency for readers.

Further, medical societies carefully and systematically develop, maintain, and communicate guidelines that impact research practice or clinical decisions, rules of hospitals and clinics, spending by government and insurers, and ultimately public health. Often these guidelines are disseminated freely through the

journals. The guidelines are developed at great expense and with significant resource burden. Utmost care is taken that they are current on the research, provide appropriate guidance based on proper methods and analysis of evidence, and bar any industry influence.

Medical societies have a long history of serving as the authoritative resource for their designated specialties. The tradition of serving as the focal point for advancing science and medicine continues today. Medical societies record and disseminate practice-changing information through journal publications, widely attended conferences, educational resources, and through multiple professional communication channels.

Maintaining this trusted role in society, at a time when disinformation is rampant, requires a significant amount of investment. Vigilance in publication research integrity and conflict of interest management not only aligns with our missions but, more importantly, gives confidence to clinicians and researchers that information we publish has been verified and is reliable.

To meet these goals and support the OSTP guidelines for public accessibility, we want to share some requests as the NIH policy is developed.

Broad Input in Policy Development

We were pleased to hear during recent stakeholder engagements that the NIH intends to include a public comment period. There are many constituent groups that will be affected by this policy and their input should be heard to alleviate any unintended and potentially negative consequences. That said, it is our understanding that public comment would not be offered until after the policy is submitted to OMB and OSTP. In light of that, we encourage the NIH to continue to engage with groups such as ours that represent clinicians and researchers. An open exchange would be helpful to discuss concerns and avoid unanticipated consequences.

Flexibility in Reuse Requirements in Publicly Accessible Content

Our request, and possibly the strongest one we have today, is that the NIH align with the OSTP's guidance to remain agnostic regarding journal business models. It would be extraordinary for a US agency to develop policies that force one business model over another with no consideration for economic harm and/or impact to societies and science communication overall.

OSTP and NIH have made it clear that there is value to the peer reviewed and journal validated version of the papers—otherwise, OSTP would have mandated preprints and grant reports. Solicitation, editorial consideration, review, revision evaluation, and ultimately publication comes at tremendous expense to societies.

In order to make the peer-reviewed content accessible without an embargo, and in recognition of our continued support in aiding researcher compliance with NIH requirements, we ask that the NIH policy refrain from requiring reuse rights under licenses that restrict our ability to establish copyright and preserve the downstream revenue associated with the final version of record.

Beyond whether a journal is subscription access, open access, or hybrid, there are other areas of revenue including licensing, commercial reprints, permissions, and advertising. The downstream revenue that we rely on to maintain journals is at risk when content is under Creative Commons licenses that allow broad re-use of content, particularly for commercial purposes.

Eligibility of Content

While some journals may decide to switch to fully author-paid open access in light of zero embargo policies, many of our journals include commissioned content such as review articles, commentaries, and editorials. Our understandings is that a forthcoming policy may cover more than original research and include editorials and invited content.

Our journals invest in putting the research in context and extend the reach and understanding of the information to a variety of audiences. We solicit editorials, invite content that explains the research, produce visuals for illustrating important points, produce podcasts with expert commentary or deep-dive interviews, and create patient pages or plain language summaries that help communicate the research for patient audiences and general practitioners that benefit from an overview in specialist topics.

These activities are expensive but contribute to the mission of our organizations to widely disseminate practice-changing research and commentary. Some of these activities also include Continuing Medical Education credit for users. Importantly, this content provides extremely valuable context and counterbalance, but as invited content it is not appropriate to charge article processing charges (APCs) for publication.

We are concerned that including editorial materials and reviews in this mandate will confuse authors and create undue financial harm to the journals and societies. We request that the forthcoming requirements explicitly exclude editorials, reviews, commentaries, etc.

Funding Available for Associated Publication Charges

We note that the NIH Data Sharing Policy explicitly allows coverage of costs associated with publishing through the grant process by including a line-item expenditure. To date, NIH allows for publication costs to be paid for with grant funding. However, based on our experience, many authors do not choose to publish open access in an environment where research dollars are stretched thin and decisions need to be made about whether to pay publication open access fees or invest in the research.

To achieve the goals of public access with zero embargo, journals will undoubtedly need to make significant changes to their publication processes and business models, likely resulting in higher publication costs. In the final policy, we urge NIH to explicitly state that full publication costs are expected and allowable grant expenditures when appropriately justified by the applicant.

We understand that to estimate these increased publication costs, a robust financial analysis should be completed. We look forward to working with our partners at NIH to help inform that analysis.

Conclusion

We want to help the NIH meet the requirements of OSTP and the goals of wide dissemination in ways that will enable our publications to continue to support the scholarly enterprise.

Our societies have a long history of engagement, collaboration, and support with the NIH and the Institutes. We assist NIH-funded authors to comply with current obligations by either batch depositing accepted papers or depositing individual papers to PubMed Central (PMC) on their behalf. We invest in

metadata creation and management. PMC has certainly benefited from the rich publication data we deposit.

We ask for the opportunity to discuss ways in which we can help authors comply with current and future NIH mandates, such as continuing to deposit materials to PMC, making corrections to the index when papers are erroneously included, or strengthening data sharing and reporting requirements for publication.

Our hope is that the NIH, in developing a new policy, will see scholarly societies as collaborators. We firmly believe that the NIH can meet their intended goals in partnership with us. We respectfully request a meeting at your earliest convenience to discuss these topics. Angela Cochran, VP, Publishing, American Society of Clinical Oncology, will serve as our point of contact for setting up a meeting. She can be reached at angela.cochran@asco.org.

Sincerely,

American Society of Clinical Oncology

American College of Physicians

American Society of Anesthesiologists

American Urological Association

American Thoracic Society

American Gastroenterological Association

Endocrine Society

NEJM Group

American Heart Association

American Physiological Society