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April 14, 2023

Lawrence A. Tabak, DDS, PhD
Acting Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

RE: Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research [NOT-OD-23-091]

Dear Dr. Tabak,

The American Academy of Neurology (AAN) is the world's largest neurology specialty society representing more than 40,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis (MS), Alzheimer's disease (AD), Parkinson's disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

The AAN greatly appreciates the opportunity to provide feedback in response to the "Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research" from the National Institutes of Health (NIH). While the AAN is supportive of the goal of enhancing public access to the results to NIH-supported research, the AAN is deeply concerned that the NIH Public Access Plan as described in NOT-OD-23-091 will be highly disruptive to the ongoing operations and article quality of *Neurology*® and *Neurology Clinical Practice*®.

The AAN is deeply concerned that the NIH Public Access Plan will result in numerous unintended consequences, resulting from the need for journals like *Neurology*® and *Neurology Clinical Practice*® to substantially modify their revenue models. The AAN believes that changes to the underlying business model stemming from implementation of the NIH Public Access Plan will likely necessitate a shift of financial responsibility from subscribers to the researchers seeking to have their research published, creating substantial additional barriers for those seeking publication. The rapid implementation of the NIH plan, specifically the elimination of the 12-month embargo, is extremely disruptive and may negatively impact the financial underpinnings of scholarly publishing and dissemination. The AAN is alarmed by the potential for the NIH Public Access Plan to create substantial inequity in those able to contribute to the body of peer-reviewed

published scientific research. The AAN is a long-standing partner in ensuring the rapid dissemination of critical discoveries and improvements stemming from NIH-supported research and is eager to collaborate with the NIH in support of policies that enhance public access, while ensuring that policy changes do not detrimentally impact the research pipeline and the ability of the AAN's journals to continue to provide critical value to researchers and the broader community impacted by neurologic disease.

AAN Publications Impacted by the NIH Public Access Plan

As the leading clinical neurology journal worldwide, *Neurology*® is directed to physicians concerned with diseases and conditions of the nervous system. The journal's purpose is to advance the field by presenting new basic and clinical research with emphasis on knowledge that will influence the way neurology is practiced. The journal is at the forefront in disseminating cutting-edge, peer-reviewed information to the neurology community worldwide. Editorial content includes Research, Clinical/Scientific Notes, Views & Reviews (including Medical Hypothesis papers), Issues of Neurological Practice, Historical Neurology, NeuroImages, Humanities, Disputes & Debates: Editors' Choice, and position papers from the American Academy of Neurology. Contents appearing solely online include the Patient Page, CME Quizzes, Podcasts, and play-in-place video.

Neurology Clinical Practice® focuses mainly on two aspects of neurologic care: 1) Clinical research on patient-reported outcomes and quality, including original research articles and meta-analyses/systematic reviews; and 2) Commentaries, reviews, and research articles on general practice, billing and coding, wellness and burnout, diversity and inclusion in the workplace, telehealth, health care policy, and financial management.

1. How to best ensure equity in publication opportunities for NIH-supported investigators.

The request for information (RFI) states that the “NIH seeks information on additional steps it might consider taking to ensure that proposed changes to implementation of the NIH Public Access Plan do not create new inequities in publishing opportunities or reinforce existing ones.” As stated previously, the AAN is deeply concerned that the NIH Public Access Plan is likely to contribute to substantial inequity in relation to who has the resources to contribute to the body of peer-reviewed, published research. The AAN believes that the NIH Public Access Plan is predicated on a belief that implementation is unlikely to have a substantial impact on journal sustainability under the existing business model. The AAN believes that the current subscription model used for *Neurology*® and *Neurology Clinical Practice*® is equitably accessible to researchers submitting their work as there are no fees for submitting a paper to either publication. Upon submission, authors are able to receive valuable feedback on the paper, prior to the paper being published in a journal within the AAN's family of journals.

The AAN is concerned that the NIH Public Access Plan will result in changes to the underlying publication business model resulting in AAN journals at least partially needing to be funded through article processing charges (APCs) and other fees borne by authors. While

this policy may result in greater immediate access to published literature for individuals who do not subscribe to the AAN's journals, the AAN believes that this policy significantly disadvantages researchers who are either unfunded or have limited funding to allocate towards the APCs and other fees that are necessitated by the NIH Public Access Plan.

In order to make the peer-reviewed content accessible without an embargo, and in recognition of the AAN's continued support in aiding researcher compliance with NIH requirements, the AAN asks 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. The value we provide to our research community is at risk when content is under licenses that allow broad re-use of content, particularly for commercial purposes.

While the NIH Public Access Plan states that "NIH currently allows funding to be used to cover costs of publication, consistent with the NIH Grants Policy Statement, 7.9 Allowability of Costs/Activities. Under the NIH Public Access Policy, NIH has clarified that publication costs, including article processing charges often associated with open access publishing, may be charged to NIH grants and contracts" provided that certain conditions are met. The AAN is concerned regarding the lack of clarity surrounding the amount of funding that will be available and the length of time for which it may be available. Additionally, it would be helpful for the NIH to precisely define the conditions under which a submitted paper may claim NIH funding and/or under which conditions the public access mandate will apply. It is currently unclear how the NIH Public Access Plan applies to a number of potential cases that a journal may encounter. The AAN requests clarification on each of the scenarios below:

- NIH-supported researchers submit for publication after grant funding has elapsed and they no longer have funding to cover APCs or other fees.
- Cases in which researchers are not funded by the NIH but cite long-running NIH studies or analyses that use data from NIH-studies.
- Instances in which an author is receiving NIH-funding for a subject other than the topic of the work that is seeking publication.

The AAN also notes that one of the conditions is that "costs are charged consistently regardless of the source of support." The AAN requests clarification regarding whether the same fees must be charged to all researchers, even those without adequate funding to cover APCs or other fees that may be covered under an NIH grant or contract. Additionally, the AAN requests clarification regarding the impact of the NIH Public Access Plan on researchers that publish research using data from NIH-funded studies after the relevant study has been concluded and as such do not have NIH support to compensate for APCs and other necessary fees. Does this requirement preclude journals from accounting for a lack of author resources in determining an appropriate fee? The AAN is concerned that in both of these cases, there will be inequitable access for researchers to access the AAN's robust peer-review and publication process.

Furthermore, the AAN is concerned that access to funding to account for APCs and other necessary fees may systematically bias the types of research able to receive peer-review and publication within *Neurology*® and *Neurology Clinical Practice*®. This is in part due to

variability in funding levels for long-standing NIH priorities and is also attributable to long-standing biases, that the NIH is currently working to address, relating to the link between funding gaps and the identities of researchers, as well as the topics chosen by those researchers.¹ Additionally, a recent study found that publishing open access drops significantly for researchers from middle-income countries whose waivers for fees are either smaller discounts or non-existent.² The AAN is concerned that the NIH Public Access Plan will exacerbate inequities for the global scientific community by forcing a large-scale shift to open access models that will price underfunded researchers out of the market.

To avoid these adverse consequences, the NIH could consider financial agreements with journals and publishers to directly cover the fees that will be required to support the NIH Public Access Plan, including compensating for changes to the underlying business model. Such agreements could then allow all authors, regardless of funding source, to continue to publish in the publication venue of their choice without directly incurring fees. Alternatively, the NIH could consider including a minimum threshold of funding on which to apply this proposed mandate.

While it may appear that the NIH Public Access Plan is the most equitable for readers, the NIH should be aware that institutional subscribers have tools to assess metrics relating to the value of a subscription, including the relative volume of journal content that is freely available to the public. Institutions then use this information to determine whether to continue subscribing to a particular journal. The AAN is concerned, absent substantial modification and clarification, that many institutions may decide not to renew existing subscriptions once this plan is implemented, necessitating a substantial modification of the existing business model for *Neurology*® and *Neurology Clinical Practice*®. Historically the value of subscribing to individual journals has been evaluated by subscribers at the point of purchase. Journals were therefore required to demonstrate their value to the end user or institution who purchased the subscription. To do so, the AAN provides metrics to illustrate the value of *Neurology*® and *Neurology Clinical Practice*®, including both usage data and impact factors. By removing the need to demonstrate quality to the end user or institutional subscriber, and instead shifting towards a business model that is at least partially predicated on fees generated based on the volume of submissions, publications will be incentivized to maximize revenues by accepting as many manuscripts as necessary without regard for quality of science or impact.

In addition to supporting the dissemination of the highest-quality and most impactful research in neurology and neuroscience, the AAN's current subscription-based publishing model supports author equity by providing equal opportunity for all authors to submit for review and publication by the journal, and benefit from the peer review process, as well as the journal's editorial oversight, production, and dissemination without charge. The AAN's peer review and publication process adds substantial value to authors as they refine their

¹ Hoppe, Travis A, et al. "Topic Choice Contributes to the Lower Rate of NIH Awards to African-American/Black Scientists." *Science Advances*, American Association for the Advancement of Science, 9 Oct. 2019, <https://www.science.org/doi/10.1126/sciadv.aaw7238>.

² Powell, Andrea, et al. "Achieving an Equitable Transition to Open Access for Researchers in Lower and Middle-Income Countries [ICSR Perspectives]." SSRN, International Center for the Study of Research, 12 June 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3624782.

submission throughout the peer-review process and to the broader neurology and neuroscience community through the development of supplemental content aimed at enhancing reader understanding of published articles. These substantial additions in value are reflected in the subscription price for AAN journals and the costs borne by the journal to engage in these activities may not be able to be recouped under the NIH Public Access Plan. As such, the AAN is concerned that our ability to continue to develop supplemental content and provide timely and robust peer-review at the same scale will be negatively impacted by this policy. Editorial operations that produce credible, validated, accessible and timely scientific papers may be weakened under the NIH Public Access Plan, due to budget shortfalls. This may result in slower peer review and/or a less rigorous review overall. Editorial offices and publishers are also addressing numerous other issues, including equity, diversity, and inclusion, scientific and editorial misconduct such as plagiarism, data and image manipulation, conflict of interests, author impersonation or fabrication, papermill output and ethical violations, all of which may be hindered under this plan.

The AAN takes its role in preserving the scientific integrity of research published in our journals very seriously. The reputations of the AAN's journals and the AAN itself relies on being a provider of trusted content. The AAN is committed to expedient but thorough review and publication of research that affects patient care. 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 the AAN's mission but, more importantly, gives confidence to clinicians and researchers that the information we publish has been verified and is reliable. Diligent peer review, management and public disclosures of conflicts, and data and figure integrity checks are vital parts of the process. These services are critical to production of a final product our members can rely upon as they conduct vital research and deliver evidence-based care, but they also require direct and substantial expense. Significant staff training and resources could be endangered if the AAN loses revenue in the form of cancelled subscriptions, insufficient total APC income, and lost licensing fees for approved reuse of content. The AAN believes it is critical that NIH account for the impact of decreased revenues on our ability to continue to offer the full range of services now protecting the scientific integrity of research published in our journals.

The AAN requests additional clarification regarding author self-deposit of the accepted manuscript on PMC as an acceptable method of compliance with the NIH Public Access Plan. While the NIH requirement is for authors to deposit, many publishers facilitate this submission to ensure the version published by the journal is the one deposited. The AAN is concerned that this policy may necessitate that journals charge additional fees to researchers for deposit to PMC to ensure compliance and consistency in cases in which the author fails to submit directly.

The AAN also requests clarification regarding NIH's statement that it will limit "inappropriate uses" of NIH-supported articles, "such as redistribution of PMC content for sale." Would this include a publisher's reuse of material from their own publications for a derivative commercial product, if that material is also hosted in PMC?

2. Steps for improving equity in access and accessibility of publications.

The RFI notes “removal of the currently allowable 12-month embargo period for NIH-supported publications will improve access to these research products for all. As noted in the NIH Public Access Plan, NIH also plans to continue making articles available in human and machine-readable forms to support automated text processing. NIH will also seek ways to improve the accessibility of publications via assistive devices. NIH welcomes input on other steps that could be taken to improve equity in access to publications by diverse communities of users, including researchers, clinicians and public health officials, students and educators, and other members of the public.”

Although the NIH is not promoting one specific publishing business model, the AAN believes that the NIH Public Access Plan will likely result in a substantial weakening of the current subscription-based model for the AAN’s journals, which may require a substantial modification of the existing model to more closely resemble a Gold OA model. The existing Green OA model with a 12-month embargo is currently underwritten by subscription, licensing, and advertising revenue. Removal of the 12-month embargo undermines the AAN’s ability to recoup investment in content-related and infrastructure costs including, stipends for editors, validation of publication research integrity, content recruitment, development and enrichment through production of ancillary material, submission and peer review systems, editorial tools such as plagiarism detection, digital platforms, and dissemination. The AAN also invests in the development of capabilities for ensuring that content is tagged and presented in a way that is useful to adaptive devices needed by users with visual and auditory disabilities.

With regard to improving access for individuals outside of the typical subscriber or society, the AAN routinely produces and/or publishes infographics, short form article summaries, and patient pages. All of the AAN’s guidelines are also published for free public consumption. Absent a direct link to the hosted page on the Neurology.org website, users on PMC have no chance to discover this content. With zero-embargo, it is possible that usage and visits to Neurology.org will fall substantially and along with it, usage of this added value content. This will discourage the AAN from continuing to invest in this content. Additionally, advertising revenue is a substantial component of the business model supporting *Neurology*® and *Neurology Clinical Practice*®. By demanding that all papers that report on NIH funded research appear in PMC with zero embargo, the NIH is restricting usage of content on the publisher sites and thereby significantly threatening advertising revenue.

As noted above, all of these activities add substantial value for researchers and readers and are reflected in the subscription cost. The AAN is concerned that we will need to investigate new means of supporting content and infrastructure costs by directly charging authors APCs and other necessary service-based charges. Furthermore, the NIH Public Access Plan erodes the longer-term value of subscriptions for journals with significant amounts of federally funded content, creating a perverse incentive related to publishing NIH-supported research in AAN journals.

In addition to clinical practice guidelines which are immediately made free to the public, the AAN routinely makes other content that is less than 12 months old freely available to any

reader. With a zero-embargo policy, the AAN will be forced to decide whether they can continue to make this content available for free. This will be true regardless of whether the AAN ultimately decides to maintain a subscription model under the NIH Public Access Plan or if the AAN shifts to a Gold OA model.

The work of converting Word files into machine readable, highly tagged extensible markup language (XML) is important, particularly for readers in need of assistive devices. Doing so also aids in search and discovery. The AAN believes there is a duplication in effort in creating XML and metadata for content reporting on NIH funded projects. To support equity in access to publications and to support automated text processing, the NIH could compensate journals or publishers for depositing high quality XML machine readable content instead of processing XML a second time via a licensing agreement. Only 11% of publishers depositing content to PMC have agreements with the National Library of Medicine (NLM) whereby they deposit already parsed and tagged XML. Whether these agreements will continue without an embargo remains to be seen. A licensing arrangement would boost compliance of deposits into PMC. While not every journal or publisher will have the ability to enter into such an arrangement, the majority, including the AAN, are already investing in XML processing.

3. Methods for monitoring evolving costs and impacts on affected communities.

The RFI notes that “NIH proposes to actively monitor trends in publication fees and policies to ensure that they remain reasonable and equitable. NIH seeks information on effective approaches for monitoring trends in publication fees and equity in publication opportunities.”

If the NIH moves forward with implementing the Public Access Plan, the AAN recommends that the NIH monitor each publication separately and avoid using average calculations. Costs involved in publishing vary across the industry and are highly dependent on specialty, as well as the nature of the publication. Even within the field of medicine, clinical journal costs vary across practitioner type and specialty. Furthermore, the costs involved in publishing in a highly selective journal, like *Neurology*® and *Neurology Clinical Practice*®, both of which receive a high volume of submissions, are vastly different from the costs of publishing in less selective journals or those with lower volumes of submissions. Costs and revenue streams vary drastically depending on many factors such as audience, circulation, ranking, article quality, supplemental materials, number of articles published, field/specialty, and distribution method.

The AAN requests clarification regarding how NIH will operationalize its approach to monitoring costs and impacts on affected communities. Specifically, the AAN requests clarification regarding how the NIH will determine the affected communities and whether it will include the entire medical publishing ecosystem and the broader neuroscience and neurologic community. The AAN also requests clarification regarding how the NIH will determine whether publication fees and policies are “reasonable and equitable.” We note that reasonable and equitable fees may vary greatly across the industry and that there is no one-size-fits-all approach. The AAN also believes that this determination may vary under different models including read and publish models and multi-payer models. Further, services rendered to authors vary by journal, which can affect the overall fee structure. The

AAN firmly believes that authors need to be given the freedom to choose the journal most appropriate for their research.

The AAN is concerned that the NIH Public Access Plan may impose substantial additional reporting burden on publishers and urges the NIH to engage in a transparent process to determine and evaluate the most appropriate monitoring method(s). There are several complications in tracking publication fees for the NIH in this scenario. We ask that any method the NIH chooses to take the following into consideration:

- It is not uncommon for authors to report NIH funding on manuscripts related to funded projects many years after the grant is officially closed. These papers will be subject to the mandate and yet no further reports (or direct grant expenses) will be accrued. However, these are direct expenses and therefore should be tracked to fully assess the impact of the proposed plan.
- Open access fees should be specifically tracked as separate from any other publication fees to truly assess the cost of the mandate. In other words, non-OA fees (such as page fees, submission fees, and color charges) that may already exist should not be included in the tracking associated with this mandate.
- Discounts given (whether by author request or as a result of society membership) and waivers should be noted in the expense tracking so as to avoid skewing the averages. The NIH should account for whether societies and journals are subsidizing author fees to understand the full impact of the mandate.
- The mandate will likely force institutions and industry to pay for publication fees on papers that report on NIH funded research. If an NIH funded author is on a paper but does not have any grant money left to pay publication fees, another author on the paper or the author's institution will have to pay. To truly understand the impact that this proposed policy is having, the NIH should be tracking exactly who is paying the fees.
- Many NIH funded authors will be able to take advantage of Read and Publish agreements that their institutions have made with publishers. As such, the grant money may not be used to pay publication fees. Still, this is an expense to the authors that ties directly to their grant funding and should be tracked by the NIH to gather a complete picture of the impact of the policy.

4. Early input on considerations to increase findability and transparency of research

The NIH is requesting “suggestions on any specific issues that should be considered in efforts to improve use of PIDs and metadata, including information about experiences institutions and researchers have had with adoption of different identifiers.”

The AAN believes it would be beneficial for PMC to only include metadata for papers that report on NIH funded research, with the accepted content, either the peer reviewed accepted manuscript or the version of record, being accessible only on the publisher site. The NIH Public Access Plan states that “NIH will continue to enable broad reuse of NIH-supported articles through services that allow for automated retrieval and downloading of full text and metadata, consistent with available license terms. NIH-supported peer-reviewed manuscripts,

other article files as license terms allow, and article metadata are made available by PMC in formats and through channels that enable text mining, large-scale machine-analysis, and computation. These machine-readable article datasets also include retractions, corrections, and expressions of concern.” Although the AAN appreciates this commitment, the AAN believes that our recommendation could achieve several important outcomes including:

- Elimination of the administrative burden on authors to make deposits in PMC. NLM could use the already existing CrossRef metadata APIs to fuel PMC as a metadata repository. Compliance would be promoted as publishers would have an incentive to invest in the metadata deposits to CrossRef as the NLM would be a strong driver of traffic to journal sites.
- Elimination of the NLM expense of “processing” content for display in PMC.
- Serving the users by aiding in discoverability of value-add related content on the publisher site, ensuring that addenda are displayed, and mitigating some of the financial damage the NIH Public Access Plan will have on societies and society journals.

If the NIH declines to implement the above recommendation, to minimize implementation burden, the AAN believes that NIH should utilize existing infrastructure already widely adopted across the industry to support findability and transparency of research. The current persistent identifier and metadata structure is supported by publishers through sponsorship and membership in organizations such as CrossRef and ORCID. Publishers also work with National Information Standards Organization to ensure metadata remains current, accessible, and included in the cost to prepare for content dissemination. By adopting persistent identifiers already in use in scholarly publishing, journals can include persistent links to critical pieces of research for the users to access.

Publishers are very interested in and have been early adopters of persistent identifiers in the scholarly communication life cycle. Digital Object Identifiers (DOIs) have been the backbone of online journal publishing since the 1990s. Much like the NIH requirement for grantees to have ORCIDs, many journals, including those within the AAN’s family of journals, require or encourage authors to use ORCID to assist in author disambiguation. The AAN’s family of journals recently updated our tracking system and authors are now required to use ORCID and FUNDREF as persistent IDs to disambiguate authors and credit funders. Further, publishers make use of FunderID and ROAR identification to again disambiguate human input data received by authors. We encourage the NIH to engage with the AAN, publishers, and the PID community of partners to use or adapt what has already been created. We highly encourage the NIH to employ DOIs for grants as well as require DOIs for datasets published.

Lastly, a commitment from the NIH to adopt persistent identifiers already in use should end the NLM practice of replacing publisher DOIs in the references of papers in PubMed. The NLM does not have permission from publishers or authors to make material changes to the deposited manuscripts. By stripping DOIs from reference links or choosing to include links to the PMC versions instead of the Version of Record, the NLM is unnecessarily restricting the user’s access to associated editorials, letters to the editor, podcasts, infographics, and other added value content hosted by *Neurology*® and/or *Neurology Clinical Practice*®.

Conclusion

As the world's largest neurology specialty society, the AAN is deeply committed to ensuring that equitable access to the most current and impactful clinical neurology research is widely available. The AAN welcomes the opportunity to continue our longstanding collaborative relationship with the NIH to ensure that any plan that may disrupt the existing business model for the AAN family of journals is implemented in a way that minimizes adverse consequences and achieves the administration's aim of promoting broad access to NIH-funded research. The AAN urges the NIH to heed our recommendations in response to this RFI to ensure continued equitable access to clinical neurology research. Please contact Patty Baskin, the Executive Editor of the AAN's family of journals at pbaskin@aan.com or Matt Kerschner, the AAN's Director, Regulatory Affairs and Policy at mkerschner@aan.com with any questions or requests for additional information.

Sincerely,

A handwritten signature in black ink that reads "Orly Avitzur MD". The signature is written in a cursive, flowing style.

Orly Avitzur, MD, MBA, FAAN
President, American Academy of Neurology