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Elias A. Zerhouni, M.D.
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Regarding: Comments of the American Academy of Pediatrics on the Proposal of the National Institutes for Health for Enhanced Public Access to NIH Research Information

Dear Dr. Zerhouni,

The American Academy of Pediatrics (“the Academy”), representing 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical subspecialists, appreciates the opportunity to comment on the National Institutes of Health (NIH) proposal, *Public Access Notice: Enhanced Public Access to NIH Research Information*.

The Academy commends the efforts being made by the National Institutes of Health (NIH) to increase the accessibility of federally funded medical and scientific research. This is an issue of great importance to pediatricians for ensuring that patients and families have access to important health information and for maintaining the momentum that the Academy and NIH have generated surrounding the inclusion of children in research and the wide dissemination of those results.

While making scientific and medical literature as widely available as soon as is practical is a goal that is shared by the Academy, we have concerns about aspects of the NIH public access proposal that we believe may have unintended negative consequences for the health and well-being of children due to the proposal’s impact on pediatric research. It is for this reason that the Academy more broadly recommends that NIH should remain committed to its efforts to make NIH funded research publicly available, but that it should do so cautiously and deliberately to ensure that the integrity of the peer-review process is preserved.

Below we separate our comments, focusing first on potential threats of the proposal to the peer-review process and second on details related to the implementation of public access.

Threats to the Integrity of the Peer-Review Process

1. Possible Impact of NIH Proposal on other Research Sponsors and its Cumulative Effect

As a world leader in funding health research, NIH’s implementation of an enhanced public access plan may lead other funding organizations to follow. If other funders did follow suit, the potential for escalating financial pressures on successful journals exists. Such

financial pressures could lead journals to consider alternative funding methods to remain viable, like author-pays systems. Such approaches have the potential to seriously weaken the peer-review process. In author-pays systems an inherent and structural conflict of interest is introduced into peer-review because the author whose research is being evaluated is also the primary source of revenue for the journal performing the review. Thus, the Academy urges for caution and careful monitoring during the implementation of any plan.

2. Six Month Access Window May be Too Risky

While the Academy agrees that all publicly funded research should be freely accessible on the Internet at some point in time and encourages all scientific publishers to adopt access windows of 12 months or less if possible, we recognize that there is not a one-size-fits-all model suitable for all publications. If journals are forced to provide free public access too close to the date of release of the print version, journal subscriptions may dramatically decrease, resulting in financial instability for the journal, and thereby causing disruption of the peer review process and the integrity of the research publication.

What is viable for weekly or monthly clinical journals is not necessarily viable for quarterly publications or research-focused publications in many fields.

The Academy encourages the access window to be as short as the publisher believes is feasible without placing each journal's continued publication at risk. Therefore, the Academy recommends that NIH does not ask publishers to adopt a "one-size-fits-all" six-month standard, and instead suggests a more flexible approach. One approach would be to start with a conservative initial time frame that was greater than 6 months. This would allow for the creation of the database and systems. It could also reduce the potential for harm by increasing the chance of identifying problems when they are still correctable. Over time, the time-frame could be gradually reduced, assuming no harm to the peer-review process is observed. Additionally, the experiences of publishers already choosing to use shorter time frames could be systematically monitored.

3. Posting Pre-Publication Articles May Lead to Misunderstandings

The Academy strongly believes that any article accepted for online publication be the final peer-reviewed and copy-edited version. Particularly for clinically-relevant findings, to publish something less could possibly place public safety at risk.

After an article is accepted for publication in most journals, it undergoes copyediting by a professional medical editor and is then proofread by the author(s) of the paper. Editors may spot errors in dosages and other critical information. They work with authors to make the communication of research findings as comprehensible as possible. Authors, in turn, re-read their papers, routinely making corrections—some of which are substantive.

Also, post-publication notices, such as erratum, need to be appended to the final manuscript. Occasionally an error is caught only after publication; in online versions, this erratum is appended to the originally published article so when a reader prints or downloads the article,

the erratum accompanies. It is extremely important to ensure such amendments be included in posted articles.

4. Benefit for Patients and Families is Unknown

Given the potential for possible harm under the new proposal it is important to consider what the likely benefit of the new proposal will be and whether the benefits outweigh the risks. While there is no way to know at this point how many people would benefit from enhanced public access, targeted users of this information likely include researchers, practitioners, patients, and patients' families. Of course, other professionals such as journalists, political activists, lawyers, and politicians may also be interested in this information. For the primary groups, however, it will be important to systematically assess during any implementation whether the enhanced public access is in fact increasing access and use. If it is found that the information remains largely used by researchers alone, then the program may need to be reassessed in that light.

Further, the Academy encourages NIH to study other mechanisms for making research freely accessible to patients in a timely manner. For example, many scientific publishers and societies have endorsed a new initiative called "Patient Inform" as a model for providing free access to patients or, in the case of children and adolescents, their parents or guardians. Specifically, the Patient Inform initiative aims to provide free and immediate access to research articles from gateway sites frequented by patients and their advocates. Additionally, however, Patient Inform seeks to provide greater context through educational and evaluative materials provided by experts in the field to help non-scientists use these research findings.

Implementation Details

1. A Distributive Model Versus a Centralized Archive: Where Will Articles Be Archived?

Rather than creating a centralized archive, the Academy encourages using a distributive model that leverages existing technology and links to articles on publishers' Web sites. Scientific societies like the Academy and scientific publishers have spent hundreds of millions of dollars developing distributed and interlinked systems of publication. We have collectively created the most stable linking system in existence through permanent, digital object identifiers (DOIs). DOIs allow links to remain intact even if Web URLs are changed. Search results would then continue to link out to the journal of record—using stable DOI-based linking—thus ensuring that all errata and supplemental materials are presented to all readers.

Thus, instead of posting authors' manuscripts in PubMed Central, the Academy recommends that NIH continue to post abstracts of articles in PubMed immediately upon publication, and provide electronic "links" to the final, edited articles on publishers' sites. This will ensure that visitors to PubMed have access to the most accurate information possible, and readers will have access to resources not contained within the author's manuscript, including supplemental data, such as video and audio files, additional data sets, slide shows, and other multimedia.

2. Print Date versus Online Posting: When Does the Clock Start Running?

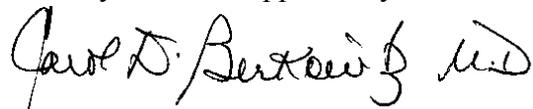
The Academy also seeks clarification concerning when the suggested closed access period begins. Especially if the NIH does not modify the 6-month recommendation, the difference in time between when a final article is posted online and when the article is printed could have a meaningful impact on certain journals. We would propose that the access window be measured from the date of release of the print version of the journal.

Conclusions

The Academy is proud of its efforts to be an early innovator in disseminating information. In fact, the Academy has been experimenting with what is now called “open access” publishing since 1997. *Pediatrics* was the first medical journal in the world to introduce an online-only section. Called the *Pediatrics* Electronics Pages, articles that appear in this section undergo the same rigorous peer-review and post-review editorial processes as articles appearing in the rest of the journal. Additionally, these articles have been, since the inception of the Electronic Pages, freely available to the public from the first day they are published. Articles of particularly interdisciplinary, international, or public interest are placed in the electronic pages so that they are immediately available to researchers and health care professionals around the world. Other content of public interest, including the Academy’s policy statements, clinical reports, and clinical practice guidelines, as well as all abstracts, are also made freely available to the public immediately upon publication. Ultimately, all articles in *Pediatrics* are available for free one year after publication. Additionally, all abstracts are freely accessible immediately upon publication.

We recognize the importance of making critical medical information available to the public, especially to protect and ensure the health of America’s children and adolescents. Supporting this vulnerable population is the Academy’s mission. To this end, the Academy supports the aims of the NIH proposal—that of providing NIH with a tool for management of its research portfolio and increasing public access to NIH-funded research. More importantly, however, we hope that the NIH will consider the Academy’s concerns and recommendations as the process moves forward, *especially as it relates to careful reconsideration of lengthening the proposed universal 6-month access window before articles are available for free public access.* The American Academy of Pediatrics stands ready to assist the NIH in any way possible, and we look forward to continuing the dialogue in order to create a system that promotes the goals and satisfies the needs of all parties.

Thank you for the opportunity to communicate our views.



Carol Berkowitz, MD, FAAP
President
American Academy of Pediatrics