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By First Class Mail/Email/Fax

Elias A. Zerhouni, M.D., Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

On behalf of the **Professional and Scholarly Publishing Division of the Association of American Publishers and the DC Principles Coalition**, thank you for meeting with publishers on **March 19, 2008**. The meeting was an important opportunity for publishers to engage with NIH, and in particular to discuss our significant concerns related to the implementation of the mandatory Public Access Policy.

We appreciate your vision for “an interconnected world of science” and continue to support efforts to enhance public access to scientific research with many of our own innovative online tools. We also appreciate your pledge to work constructively with publishers to fully address copyright concerns and make the policy work. However, we are troubled both by your unwillingness to acknowledge the Public Access Policy’s flawed legislative process to date and by your lack of concern for any dislocation that will result from adhering to NIH’s “implement and steer” approach for this major shift in policy. Improper implementation of this sweeping mandate has **serious implications for all stakeholders in the research community** (publishers, authors, the public) and for science itself. It is important that these implications be fully considered and addressed as soon as possible.

Publishers left the March 19 and March 20 meetings with key policy and implementation concerns still to be addressed. For example:

- **Copyright.** Blanket requirements in grant contracts would effectively deny authors and publishers the benefits of their copyrights—the most fundamental of which is the ability to decide how and in what form their works may be distributed—in conflict with fundamental copyright principles and without compensation for the value added by publishers and editors. In effect, the application of the NIH policy is an imposition of an extraordinary and unprecedented exception or burden to the copyright works—and thus diminishes their value for any journal

business model that relies on exclusivity to drive traffic, advertising and subscriptions. The NIH policy essentially mandates a business model that can accommodate this “burdened” copyright, a model that must be based on up-front submission or publication charges, rather than the current models of the vast majority of journal publishers. This does not seem to us to be consistent with the legislative mandate to implement the NIH policy consistent with copyright. Other alternatives to the NIH policy of mandated centralized posting on PMC can and should be considered, alternatives that would still be consistent with the legislative mandate of public access within 12 months of publication.

- **Quality Control and Compliance with Publisher Policies.** Many manuscripts currently appear on PubMed Central (PMC) in violation of publisher policies. How will NIH ensure under the new public access policy that individuals post the correct manuscript version to PMC to be publicly available at the correct time, consistent with publisher agreements? For publishers submitting directly, how will NIH ensure that articles will not be accepted from individuals or entities other than the publisher?
- **Scope.** The revised mandatory public access policy now calls for submission of review articles. This is of concern to publishers especially since NIH previously encouraged us to add review articles to our journals as a way to protect our subscription base under the voluntary policy. Editors commission the review articles based on the scientific expertise of scientists; they are not based on specific research projects supported by NIH research grants. Furthermore, requiring that review articles be included will seriously undermine the many journals that publish review articles only.
- **Repurposing.** Changes made by NIH or authors that will result in variations from the original manuscript are of considerable concern for a number of reasons, not least of which is the potential introduction of errors. NIH needs to ensure that no changes, such as substantive editorial changes, are made to the manuscripts other than obvious errors in NIH production process or perhaps improved graphics for related illustrations. Links to other databases also raise concerns about changing an article’s principal context and focus. NIH needs to identify precisely how manuscripts will be linked to databases and other resources to ensure the editorial integrity of the underlying work.
- **Patient education.** Although we understand that the principal motivation of the legislative mandate to be patient information and education, the NIH policy implementation does not address this need directly (focusing instead on building researcher infrastructure). Publishers have been working actively with voluntary health organizations (VHOs), as you are aware, and we believe more should be done in this area by NIH, hopefully working with publishers and VHOs.
- **Piracy.** Third parties could commercially exploit content that appears on PMC without the consent of the publisher. What safeguards will NIH put in place to prevent copyrighted material available on PMC from being altered, pirated, made into derivative works, redisplayed, republished, resold or used for any other commercial purpose?

These represent only a few of our many practical concerns related to implementation of the mandatory policy. I have enclosed for your reference a more complete “checklist” of publisher questions as well as the previous comments PSP submitted to NIH in advance of the March 20 meeting. We hope it is clear that publisher concerns reflect not only critical issues related to the spirit and protection of copyright but those aspects affecting day-to-day management of the policy and how effectively it achieves its stated objectives. We believe that we can work with NIH to

arrive at practical solutions to these concerns, but that will require regular, ongoing consultation and discussion.

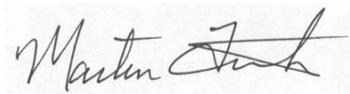
In light of the substantial nature of these questions and NIH's commitment to the advancement of science, we believe it is important that NIH fully address these questions as soon as possible. We are pleased that you noted in our March 19 meeting that you wanted to establish an open process to "get the spirit of the public access policy right" and that NIH has chosen to solicit the public's views through the Request for Information (RFI) process. While publishers continue to believe the best way to do so is through a full notice-and-comment rulemaking proceeding, completed before implementation, and reserve our rights with respect to that approach, we look forward to a positive and constructive interaction with NIH that will result in balanced implementation of the new public access mandate in a way that addresses our concerns, advances science and benefits the public.

You can contact me at 202/220-4544 or adler@publishers.org, and I look forward to hearing from you at your earliest convenience. Dr. Frank can be contacted at 301/634-7118 or mfrank@the-aps.org.

Sincerely,



Allan Adler
Vice President for Legal and
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Martin Frank, Ph.D.
Coordinator, DC Principles Coalition and
Executive Director, American
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Cc: HHS Deputy Secretary Tevi Troy
Cc: HHS Acting General Counsel James Stansel

Implementation of the NIH Mandatory Public Access Policy Publisher Concerns

NIH needs to ensure that the implementation of the policy will respect the basic principles embodied in copyright and not undermine those rights that provide incentives for publishers to invest in peer-review, publishing and the communication of scientific and medical research. Without review and significant changes, the mandatory Public Access Policy could have unintended and undesirable consequences. The issues that must be addressed include:

Consultation: NIH Dialogue with Publishers, Societies and Authors

Non-profit and commercial publishers, societies and researchers are not only seriously affected, but also critical to the proper implementation of the policy. A formal and ongoing consultative body that includes stakeholders, and with Administration and Congressional oversight, will help ensure that a successful public access model is developed. We urge NIH to conduct regular meetings with publishers and provide regular progress reports on the matters raised by publishers.

- Many investigators are not aware of the new policy. Does NIH have a formal mechanism and the necessary resources to handle the questions that will arise from authors and journals?
- What is NIH's timeline for **amending** this policy moving forward?
- What mechanism will NIH put in place to continue the dialogue with publishers that will help ensure this policy is "implemented and steered" effectively and that publisher concerns are addressed?

Overview: Copyright Concerns

Journals add considerable value to published papers by managing peer review and providing copyediting and design revisions to improve the validity of the published product, benefiting researchers, the public, and the scientific community. The expense and effort of this process is supported entirely by the journals, not by NIH. Under the mandatory policy, significant copyright interests are being taken from publishers, without compensation for their investments. Other related responsibilities undertaken by publishers that bolster the scientific enterprise and thereby add value to individual scholarly works include: editorial selection of manuscripts to be published, marketing, distribution, and preservation. Publisher business models involving subscriptions, transactional paid access to individual articles, and advertising support within traditional publishing and on publisher web sites driven by the distribution of "new" articles, all of which depend on traditional copyright protection, will be impacted by the policy as announced.

- Shouldn't NIH support the full value of copyright and their use in business models including those which involve driving traffic to a publisher site, and permit linking to publishers' web sites, rather than requiring deposit at PubMed Central?

Brand Protection, Repurposing and Piracy

It is critical that NIH implement the Public Access Policy in a manner consistent with intellectual property protection and the intent of the related Congressional mandate, and work with publishers in ensuring such implementation.

- What mechanisms will NIH put in place to ensure that any revisions to copyrighted materials such as reformatting, enhancing, linking or otherwise changing the articles respect the integrity of the copyrighted content it receives? What assurance will NIH give that this will be done in accordance with guidelines agreed to with publishers?
- Will NIH identify precisely how manuscripts will be linked to databases and other resources, and which databases? Publisher concerns about links include: a) Would links within the article obscure the information in the text? b) Would it change the editorial emphasis by seeming to suggest that certain information within the article is more important than other information, simply because there is a link? c) Would it be appropriate to change that emphasis in the context of the research and the article's focus?
- How will NIH ensure proper protection of publisher or society trademarks and branding? Not only has there been no affirmation of these markers of quality, but all too often branding information is missing, potentially misleading users to the erroneous conclusion that the NIH is claiming copyright, or that the content is in the public domain.
- It is critical that NIH respect the rights of copyright holders to stipulate what NIH will or will not allow related to third-party use of its works. Will NIH ensure that manuscripts are not distributed to other sites around the world besides PubMed Central? Will NIH implement guidelines that explicitly prohibit third parties from exploiting content that appears on PMC without the consent of the publisher?
- How will NIH prevent piracy of the articles from PubMed Central? Third parties could commercially exploit content that appears on PMC without the consent of the publisher. Will NIH prevent copyrighted material available on PMC from being altered, pirated, made into derivative works, redisplayed, republished, resold or used for any other commercial purpose? What will happen if piracy is discovered as a result of downloading of content from PubMed Central and will NIH notify publishers?
- If deposited content will be "mirrored" to other sites outside the U.S., after publisher approval, how will the sites be established, and how would national and international copyright considerations protect rights holders? What guidelines will NIH agree to with publishers before any distribution of copyrighted content occurs on PMC international mirror sites?

Compensation

While taxpayers pay for the scientific research on which journal articles are based, non-profit and commercial publishers expend hundreds of millions of dollars a year in the peer-review of manuscripts and in preparing journal articles for publication and timely dissemination in print and online. The cutting-edge research that the many societies publish is rarely obsolete within a year, and may have a shelf life of five to ten years. It is imperative that NIH provide reasonable compensation to publishers for their investments and the well-recognized value that they provide to peer-reviewed manuscripts based on NIH-funded research.

- What latitude will NIH have in negotiating terms and conditions directly with publishers and other rightsholders who might wish to undertake direct licensing arrangements with NIH that would enable the deposit of copyrighted works on behalf of authors? Given that NIH's policy would amend many journal copyright policies and effectively reduce the value of those rights, will NIH be empowered to negotiate such licensing terms, including publication charges/payment, as certain non-government funding agencies have done?
- The policy provides for publisher deposit of final peer-reviewed manuscripts on behalf of authors, and includes allowance for grantees to use grant funds in the payment of publication fees. How will such funds be identified in the grant and what has NIH budgeted per year for such costs over the next five years?

Scope

The statutory language of the mandatory Public Access Policy applies to "all investigators funded by the NIH," yet does not specify whether the NIH funding is in whole or in part. NIH takes the view that the policy applies to investigators with any NIH intramural research funds or any amount of direct costs funded by NIH, even if the funding is insignificant and supplemented by other public or private sources.

- If there are other funders, what will researchers be expected to do if these other sources oppose the posting of their funded work on PubMed Central?
- Will NIH agree to stipulate that its requirement for the deposit of peer-reviewed manuscripts in PubMed Central only applies when NIH funding represents substantial funding for the research on which the scholarly work is based?
- The policy also holds that "Principal investigators and their institutions are responsible for ensuring all terms and conditions of awards are met." Yet, this includes the submission of articles that arise directly from the investigators' NIH-funded research *even if they did not author or co-author the publication*. In fact, NIH-funded investigators and institutions are being held responsible for making sure these other authors are "aware of and comply with" the NIH policy. How could they comply with this provision?
- What will the repercussions be for investigators and journals that do not follow the process?
- Will NIH modify its guidelines to state that its deposit requirement only applies to peer-reviewed manuscripts that report findings of empirical research and does NOT apply to literature reviews?

Integrity of Research, Quality Control and Meaningful Public Access

The NIH posting of peer-reviewed manuscripts accepted for publication compromises the quality of scientific publishing by ultimately making available two different versions of scientific papers. The first is the inferior, peer-reviewed manuscript that has not yet benefited from the final copyediting, fact-checking, and proofreading required for formal publication, and the second is the definitive, publisher-authenticated version. Given the new policy requiring deposit of NIH-funded manuscripts in PubMed Central upon acceptance, there are some procedural issues that are unclear. In addition, the benefit of access to manuscripts by patients and the general public has never been fully assessed and alternatives such as lay summaries may be far more useful. NIH should ensure

that the implementation of the policy is truly beneficial to the public and does not displace other useful models.

- How will the NIH know the final month of publication when the month is not always established upon acceptance to a journal?
- Many manuscripts currently appear on PMC in violation of publisher policies. How will NIH ensure under the new public access policy that individuals post the correct manuscript version to PMC to be publicly available at the correct time, consistent with publisher agreements? Will NIH ensure that embargo and posting policies are implemented on a journal-by-journal level or at least publisher-level? Will NIH provide a detailed description of the process at NIH to monitor and ensure prompt take-down of manuscripts improperly submitted?
- For publishers submitting directly, how will NIH ensure that manuscripts will not be accepted from individuals or entities other than the publisher?
- How will NIH ensure that researchers are not misled as to the accuracy and validity of manuscripts on PMC? Will there be pointers to final published versions on publisher sites? One possibility is for NIH to develop a special section within PMC for members of general public/patients to “land” on suitable information for patients and “disclaimers” that the PMC author manuscript represents only a small part of the literature, with references and links to VHOs, Patient Inform, publisher sites.
- How will NIH deal with plagiarism and ethics issues? Will NIH establish guidelines in consultation with publishers on how to deal with corrective notices, corrigendum, and retractions?

Cost

The mandatory public access policy will not change the cost of scientific publishing, but will shift the burden of that cost away from scientific publishers and onto authors and the government, in other words, onto taxpayers.

- NIH faces funding shortages from the federal government. How much will it cost to effectively implement this policy?
- Does this cost detract from funds to grantees actually conducting the innovative research that advances science?

Measuring Impact and Effectiveness

The policy will affect all stakeholders in the scientific research community and may have a particularly severe impact on small society publishers as subscription revenue will likely decline with increased free access on PubMed Central. It is important for NIH to ensure that content on PMC will not displace the definitive published version and that publishers brands are not diminished. NIH needs to ensure that PMC does not undermine the viability of journals whose economic stability varies widely.

- Will NIH provide publishers with detailed and robust PMC bibliographic usage statistics that will enable them to assess the impact of PMC usage on their subscriptions?
- What oversight or governance will monitor whether NIH's performance in pursuit of its intended purpose a) is met; b) is not costly for the taxpayer; c) is not burdensome on research investigators; or d) does not have a negative impact on the integrity of the scientific and medical literature (e.g. errors and versioning problems introduced, economic harm to journals and publishers)?
- What steps will NIH take if it is found that its Public Access Policy is hurting rather than advancing scientific research?