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Response to Public Notice: NOT-OD-04-064
"Enhanced Public Access to NIH Research Information"
Submitted by: The American Society for Pharmacology & Experimental Therapeutics

November 8, 2004

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

Dear Dr. Zerhouni:

As President of the American Society for Pharmacology & Experimental Therapeutic (ASPET), I write on behalf of ASPET Council in response to Public Notice: NOT-OD-04-064, "Enhanced Public Access to NIH Research Information." ASPET, established in 1908, publishes five journals and supports over 4,700 members engaged in research in academia, industry, and government.

While ASPET believes in the principle that the public has a right to seek access to the results of NIH funded research, ASPET does not support the NIH proposal in its current form. ASPET does not believe that the NIH should inject itself into scientific publishing by enforcing proposals that could have potentially adverse consequences to intellectual property protections, destabilize current scientific publishers including not-for-profit professional societies, and perhaps retard scientific progress. ASPET has not seen any evidence that the NIH has adequately evaluated the genuine costs of this action for a need that has not been proven.

ASPET and many other not-for-profit professional scientific societies publish journals reporting the results of high quality research studies in our area of interest. This is done as a service to our members and to the broader scientific community, with the objective of increasing understanding and promoting the communication of new knowledge throughout the scientific community. The society evaluates and critiques submitted manuscripts and then provides copy-editing and other services for final publication. The costs of these activities are justified by the added value to readers and authors created both by the evaluation and initial critiques provided by well-qualified experts and from the improved clarity of presentation added by the editorial process. At present, NIH research funding does not cover the full costs of these additional values provided by the scientific publication process. This cost is recouped by publishers in the form of a reasonable subscription charge paid by readers who derive a benefit in the form of increased knowledge leading to practical and sometimes financial benefit.

We have several concerns regarding the specific proposals contained in the Public Notice, NOT-OD-04-064, concerns that have not been addressed rigorously by proponents either in the notice or elsewhere. First, it has not been established that the proposal addresses a real public need. There is no documented evidence that a substantial number of persons have requested immediate free access to publications from NIH supported scientists, or that the lack of such access has caused a

significant delay in the access of patients to novel therapies. Under the present system authors and publishers both gain benefit by making available rapidly the results of any study that might offer an immediate advance in therapies, and usually do so with as much publicity as possible. The NIH proposal does not address how the public benefits from free access to highly technical scientific material that the lay person would likely not understand or be able to apply with any clinical relevance to their own personal medical needs.

Second, there is no credible estimate of costs. Funds that will have to be committed by NIH to support this proposal are likely to reduce the funding available for the conduct of investigator-initiated research. For productive researchers, the proposals will result in considerable cost-shifting, with some researchers possibly unable to find funds to cover the costs of publication of all their research results. Significant limitations in the analysis of the costs of the new proposals include a failure to consider the costs to the NIH implicit in the implementation of proposed policy in the form of technical and manpower resources, to scientists in the form of increased manuscript publications costs that may not be reimbursed by all funding agencies, and to society journals in the form of potential loss of subscriptions. Specifically, there is inadequate consideration of:

- The costs to NIH of supporting the infrastructure necessary to maintaining unlimited access to manuscripts from all NIH-funded research in relatively inaccessible manuscript form.
- The costs to professional society publishers who may lose a significant part of their subscription base as a result of the loss of exclusivity in publication (who will pay for a journal subscription if free access to many articles in the journal is freely available within a few weeks?). With reduced subscription income, journals will have to charge all authors a high publication fee. The costs of publication will be transferred from a large number of subscribers who gain benefit from access to the information to a small number of publishing authors.
- The costs to the NIH of supplementing each funded grant with adequate funds to cover the total costs of manuscript publication. How will patients benefit by diverting money from research on disease to the underwriting of publication costs?
- The costs to authors who are not supported by NIH research funds to cover the costs of publication of their research results. These authors will have to find the additional funds to cover their increased publication costs from other sources.
- The potential impact on young scientists who are particularly likely to be included among those without NIH support. They may find that they cannot afford to publish in prestigious journals that can ensure the widest distribution of their results and thus facilitate their career progression.

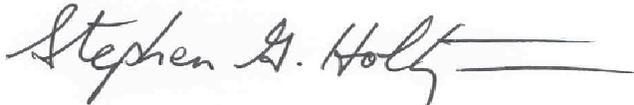
We are also concerned about the philosophical implications of the proposed requirement that all published research generated in all or in part from studies conducted with funds provided by NIH will be published in a federally mandated scientific repository of information.

- A federally mandated repository runs counter to the idea of academic freedom in scholarly discourse; the potential exists for government and agency censorship of publishable material and could compromise the integrity of the scientific record.
- The notice ambiguously states that grantees provide NIH with manuscript copies "...if the research was supported in whole or in part by NIH funding." NIH support of published research may only be a small fraction of the total support for the project; in some cases only one author of many is in receipt of NIH funding.

- The notice ambiguously “requests” grantees and investigators to provide NIH with electronic copies of all final version manuscripts...” However the request sounds like a requirement because the notice further states “submission of the electronic versions of final manuscripts will be monitored as part of the annual grant progress review and close-out process.”
- What assurance is there that the accepted manuscripts in PubMed Central will be free of scientific error, causing incorrect information on an official government website? Who will be responsible at NIH to make certain that changes to published journals be amended to the paper in the NIH archive? Why are taxpayers asked to pay for services already performed by the publishers?
- Has there been a detailed legal review of the intellectual property implications that providing free access to research manuscripts entails? And what would the impact be on collaborative research teams from around the world?
- How would issues of conflict of interest be resolved? Under the NIH plan, any author whose research is being evaluated by a journal becomes the main source of that journal’s income. This threatens the peer-review process and ultimately undermines the integrity of research.

ASPET believes that unless and until a real problem is determined to exist there can be no consideration of the options available to address the issues outlined in the NIH proposal. The current NIH granting process contains reporting provisions that already ensure that the funding institutes are fully informed of the outcomes of research studies. Authors already have many incentives to publish their results rapidly and to report these results immediately to NIH. To ensure that members of the public and their medical representatives can gain early access to research studies supported by NIH that could impact on their medical treatment options, ASPET recommends that professional not-for-profit societies and private for-profit scientific publishers work together to find a compromise proposal with fewer negative consequences for the journals than in the current proposals. ASPET recommends that the proposals in NOT-OD-04-064 be withdrawn.

Thank you for the opportunity to address our concerns.
Sincerely,

A handwritten signature in black ink that reads "Stephen G. Holtzman" followed by a horizontal line.

Stephen G. Holtzman, Ph.D.
ASPET President