



November 12, 2004

Public Access Comments
National Institutes of Health
Office of Extramural Research
6705 Rockledge Drive, Room 350
Bethesda, Maryland 20892-7963

Re: Enhanced Public Access to National Institutes of Health Research Information

Dear Dr. Zerhouni:

On behalf of the American Society of Hematology (ASH), I am writing to comment on the notice regarding the National Institute of Health's (NIH) proposal for "Enhanced Public Access to National Institutes of Health Research Information," as described in the Federal Register on September 17, 2004 (Volume 69, Number 180, Page 56074). ASH represents over 13,000 members that contribute extensively to and rely heavily upon research findings, data, and other information that are reported in scientific journals. While ASH is deeply committed to public access of scientific information, we oppose this NIH proposal. We are concerned that there has been no problem described to which the proposal is addressed; the costs and benefits of the NIH proposal to create an additional online repository of research findings have not yet been adequately studied; and that the NIH is proceeding administratively to implement a policy that could have significant adverse effects on researchers, the professional societies that publish scientific journals, and federal research funding. Further, we question whether the NIH proposal will achieve its stated goal of helping to improve the health of patients and the public.

Through our society's activities, programs, and publications, ASH has demonstrated its interest in providing researchers, patients, and the public with access to science. ASH's journal *Blood* has amply demonstrated the society's commitment not only to archive our journal, but also to move into the electronic age by making the content of the journal electronically accessible. ASH provides free access to back issues of its journal after a 12-month embargo period. Articles that are less than 12 months old and require a subscription are accessible via a pay-per-view option. An interested non-subscriber reader can immediately gain access to any abstract for free or to an article for a modest fee. In addition, ASH is a member of the DC Principles coalition that supports a variety of measures to make content available on an expedited basis for patients and others who have compelling needs. For example, any clinical article published in our "How I Treat" section as well as the "Inside Blood" pieces that summarize important advances and often build a bridge to clinical content are free at the moment of publication. Moreover, five of the most important research articles in any issue, as selected by the Editor, are also free. In this way, breakthrough studies that could immediately help patients and their families are freely available to everyone on the day of publication.

2004

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What is the problem being addressed? The fact is that published scientific literature is routinely and readily available to all who need and want it through paper and online subscriptions, online licenses, electronic pay-per-view, individual document delivery and free interlibrary loan. Many publishers including ASH have already made considerable amounts of original biomedical research openly available via the Web. This issue presented by the NIH proposal is not one of access, but of who will pay for the cost of publication and whether government should force publishers to change from a business model that relies on subscriptions and advertising revenue to an untested model that depends on individual author-researchers to pay for the costs of publication.

While we continue to seek new innovative ways to provide greater public access of science, we believe NIH has not presented compelling evidence why it should require an “author pays” publishing model and create an additional biomedical research archive. ASH shares the following concerns and questions about the NIH proposal with others in the research and patient advocacy communities:

What will be the impact of the NIH proposal on non-profit society journals? ASH is deeply concerned that the NIH proposal will significantly affect our journal’s business model as well as similar nonprofit societies and their publications that rely on subscription and advertising income to support their operations.

Presently, about two-thirds of the revenue coming from our journal is from subscriptions and advertising; 13% are from author charges. ASH makes the content of all *Blood* articles free after 12 months based on analyses that has convinced us of the negative financial impact that shorter periods would have. The NIH proposal for open archiving will result in some customers canceling their subscriptions to wait the abbreviated time for free access. Consequently, advertising would be reduced because the paper circulation would be decreased and most advertisers do not believe they get the same return through internet advertising. This, in turn, would give ASH and other publishers little choice but to enact greater author fees to compensate for lost revenues and cover the costs of publication.

We are additionally worried that the scope of this proposal is not merely to require on-line publishing within six months, but the ultimate goal of open access advocates to mandate immediate free on-line publishing to everyone. That broader proposal would result in removing all revenues from subscriptions and most advertising and would undermine the economic foundation of established journals and their ability to publish. Moreover, in the case of a journal like *Blood* that pre-publishes all manuscripts upon acceptance, the proposed six month period actually becomes two months after publication (allowing for the to edit, format, etc.) virtually eliminating all subscriptions.

We strongly urge NIH to examine the impact of this proposal on not-for-profit journals. By imposing too short an interval between publication and free access, the very existence of some journals, and the associations that use subscription and licensing funds from these publications to support their educational missions may be threatened. We believe that if the NIH works with ASH and other stakeholders, a mechanism can be developed

to continue to increase access to NIH funding research without threatening the ability of non-profit professional societies to publish high quality scientific journals.

What are the costs of creating an additional online repository? We note that the costs of creating and maintaining the online repository NIH describes in its proposal are unknown. Although various parties have made estimates of the costs, these range widely, and none is backed by a thorough analysis of the associated capital and human resources needed. The most recent estimate provided by NIH officials was \$2 million in FY 2005 and \$2-\$4 million in subsequent years. ASH is very concerned that the cost of the repository could be more significant than anticipated. Prior to implementing such a policy, we believe NIH needs to provide more details regarding its cost estimate. For example, does the estimate include all staffing and technical costs? Does it include the cost of developing and maintaining state-of-the-art archival and search capacity? And, most importantly, would funding for this proposal come out of, or be in addition to, funding available for NIH research grants. ASH would strongly oppose any initiative that involves diverting research grant funding into maintaining an online repository, particularly in this time of increasingly scarce research dollars.

What will be the impact of the NIH proposal on author-researchers? The proposal raises several questions about how it would affect author-researchers. Prior to implementing this proposal, we strongly believe the NIH needs to examine these questions and provide an assessment of the plan's impact. Questions include: How would the proposal affect multi-author papers? How would the proposal affect the publication of results from research funded by multiple sources in addition to NIH? How would the proposal affect academic freedom in the university research and publishing settings? Would authors of research papers continue to have the right to make their own choices among journals or other venues of publication? Will author-researchers have less money to spend on research if a portion of their funding must be earmarked to cover the costs of publication? Will this lead to reducing the number of articles published by prolific authors?

Will the NIH proposal compromise the integrity of the scientific record? The proposal requires posting what NIH terms "final manuscript" -- commonly referred to as the "raw manuscript" by publishers -- within 6 months of publication. We believe this proposal does not recognize the quality control and significant changes that journal publishers make to correct errors in manuscripts after the peer review process. We are extremely concerned that using any version other than the true "final" one will cause confusion, at a minimum, and could significantly compromise the scientific record. This view is widely shared by journal publishers who recognize that copyediting, proofing, reference checking, formatting of images, tables and data sets, and other functions performed by publishers add real value to manuscript. While the NIH proposal would allow publishers to request that the author version be replaced in the PMC archive by the final publisher's copy with an appropriate link to the publisher's electronic database, we believe letting the author version remain in the archive would lead to confusion for authors and potentially misinform readers.

We also do not understand how this policy would improve the current publishing process. For example, ASH's journal currently posts raw manuscripts within a couple of weeks of acceptance. Once finalized and published, the raw manuscript is hidden behind the final version to avoid confusion. In terms of providing a gateway to research findings, we note that 3,000 of the 4,500 journals in MedLine already provide links from abstracts to final articles on journal websites. We believe NIH would do better to find ways to enhance this program since it reinforces the role of the finished article as the authoritative version of record.

What will be the impact of the NIH proposal on patients and the public? ASH questions whether the NIH proposal will, in fact, achieve the agency's stated goal of improving the health of patients and the public. We note that there is no evidence to demonstrate the efficacy of online access to primary biomedical literature for improving either practice patterns or patient outcomes. Rather, effective patient education requires clear and consistent messages of applicable information.

If NIH's desire is to expedite transfer of information from federally supported research to taxpayers, other approaches seem more appropriate. For example: ASH is working with several patient advocacy organizations and other publishers on a project, "Patient Inform," a major private sector initiative to provide patients with meaningful analysis of the latest clinical research. Rather than pursue an effort that will have a marginal, at best, impact on the public's understanding of research, to show its commitment to public access of scientific information, NIH should encourage NLM to work with Patient Inform. Secondly, NIH could examine its patient websites and how they could be improved in some way or marketed more effectively so patient groups will turn to this reliable source of information. Thirdly, NIH could invite patient groups to suggest way in which information could be transferred more effectively, which, in turn, could lead to some demonstration grants.

What are the long term policy consequences of the NIH proposal? The NIH proposal could have many significant policy consequences that need to be explored and understood. For example, is a central government-run repository of scientific research the best approach? The NIH proposal advocates the transformation of PubMedCentral, which currently houses content from only a small fraction of the biomedical literature, into a huge central repository without looking at the consequences. Is it appropriate for the government to favor one publishing business model and thereby dictate how, when, and potentially where researchers publish? Will this model lead to the government deciding what research gets published as well?

Further, what is the impact of the NIH proposal on copyright? What would happen if the principle that "the taxpayers have already paid for the research" were applied also to patents, pharmaceuticals, and other products of government-funded research? ASH is concerned that the NIH proposal would reduce the value of the license or copyright transfer that our journal authors make, by eliminating the exclusivity of the grant and making it impossible for us to recoup investment. This could set a dangerous precedent with respect to an independent investigator's control over patent and trademark rights. It


also runs counter to established law that affords investigators and their employers the right to benefit financially from the results of federally funded research conducted under their auspices.

Finally, what will be the impact of the NIH's proposal on U.S. jobs and exports, particularly if other federal funding agencies follow suit. In addition, we wonder if any analysis has been completed on the impact of this proposal on the loss of federal revenues derived from the Unrelated Business Income Tax (UBIT) currently paid by non-profit societies.

In conclusion, ASH believes the NIH proposal will have significant, wide reaching, and potentially detrimental consequences while not meeting its stated purpose. ASH is concerned that the NIH proposal was not developed through an open process, but by a small number of hastily developed invitation-only meetings. There have been neither Congressional hearings nor any financial analysis of the proposal. We are especially troubled that this proposal does not include the basic elements required of any NIH – funded proposal – a clear evidence-based articulation of the problem to be addressed, evidence showing that the proposed solution is evidence-based, discussion of less intrusive alternatives and a detailed budget. As a result, many of those most affected have not been able to ask questions, voice their concerns, and, importantly, engage in a dialogue with the NIH about how we can work together to support our shared goal of providing access to science.

ASH recommends that the NIH delay implementation of its proposal pending a thorough analysis of its costs, integration with existing online literature, and impact on researchers, professional societies, and patients.

Sincerely yours,

A handwritten signature in black ink that reads "Stanley L. Schrier". The signature is written in a cursive, slightly slanted style.

Stanley L. Schrier
President