



# The NEW ENGLAND JOURNAL of MEDICINE

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Elias Zerhouni, MD, Director  
The National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Dr. Zerhouni:

The Massachusetts Medical Society, as publishers of the *New England Journal of Medicine* has for years supported and upheld the principles of broad access to our medical information on a weekly basis. The research articles we publish are instantly accessible online for free in 120 lower-income countries; seen by tens of millions around the world, including our 500,000 regular readers; and available for use by educators in classrooms and clinics. In addition, for four years we have offered the research articles we publish free on our Web site six months after the publication date. This includes all research articles, not just those funded by the NIH.

Our own actions support the broad principles behind the efforts of the NIH to increase the public's access to medical information. However, we believe the proposed policy change before the NIH, as currently structured, could have several negative unintended consequences that could threaten the ability of medical publishers and societies to continue to support and protect high-quality published representations of scientific research. We urge the NIH to move cautiously and open up a deeper dialog with key constituent groups so we can serve the interests of patients, science and medicine while and maintaining the integrity of the medical record.

We ask you to consider specifically the following:

**The current proposal would diminish both publishers' ability and incentive to protect the integrity of their portion of the scientific record.**

By putting readers first in the editorial and economic equation, medical journals are highly motivated to protect the integrity of their portion of the scientific record. If scientific research is published without active, interested and well-funded groups enforcing copyright, any company or commercial interest can effectively re-distribute content selectively or in any form or context they choose. We know this to be true.

Recently the public was victimized by an overwhelming campaign centered on false statements about growth hormone research the *Journal* had published. Current copyright and trademark laws allowed the *Journal* and prosecutors – at substantial private and public expense – to take action and warn the public of such practices. The accuracy, integrity, and public presentation of the research the *Journal* publishes are protected by our copyright, allowing clear defense of research integrity.

The proposal before the NIH would create a redundant repository with ineffective safeguards and undercut our ability to defend scientific papers from misuse by commercial interests. To make clinical research available to all is not enough. Putting science online with little protection against abuse or misuse by commercial interests is not, in and of itself, going to help patients make better choices or give clinicians better insight into patient care.

**The policy that NIH is contemplating has the potential to force publishers away from a subscription-based publishing model to an author-pays model of open access, casting doubt on the integrity of published research.**

Free access to NEJM content after six months works for us but there are many differences between the NEJM and other medical journals. Smaller medical societies with monthly or quarterly journals have legitimate concerns about the potential negative impact this could have on their ability to support their peer review and distribution. Domestic or international libraries could decide to stop subscribing to these publications forcing publishers to move away from a traditional “user pay” model to an untested “author pay” approach. There are legitimate concerns about the sustainability and credibility of this new model of open access. For example, there is a fundamental conflict of interest in a model where the publisher is only paid when an author publishes. This creates an incentive for the publisher to accept more papers, and perhaps compromise with authors to move papers forward.

When a publication is paid for by its readers, the editors are incented to ensure that conclusions are not overstated or misleading, that results are put into the proper content for clinical practice and that a dispassionate peer-review process has informed editorial selection. The NIH should consider carefully any position that may tip the scales to this new method of supporting peer review.

**The current proposal raises serious and important questions about the proper role of the federal government in the publication of scientific research.**

Under the current proposal, the entity that funds the research would also act as its publisher. This raises the question: What safeguards exist to protect politically inflammatory research results? For example, what if public funds produced a study undermining an administration’s political position on stem cell research? To what extent will the administrative and operating philosophy of the proposed repository be subject to changes when the leadership at the NIH, in Congress or the White House changes? This is uncharted territory. We ask the NIH to think very hard about the implications of having the federal government own both the process of research selection *and* its publication.

**The current proposal has failed to address several important logistical hurdles with regard to authorship and manuscript editing**

The proposed policy change, as currently constituted, would allow authors of accepted papers to send their manuscripts to the NIH upon acceptance at a publication. But the mechanism for validating that the author's

claim of acceptance at a certain journal is unclear, and appears to rely solely on accurate reporting by authors. There do not appear to be any safeguards to prevent false claims of authorship whether by honest error or fraud. The current language also does not appear to take into account the fact that numerous important changes to a research article often occur after "acceptance" by a medical or scientific journal, including language changes, statistical checks, editing, and corrections that often provide substantive change, important nuances, or highlight crucial implications in the results.

**The proposal also appears to put the NIH in the position of having to coordinate, manage and enforce the disparate media policies in place at various medical journals.**

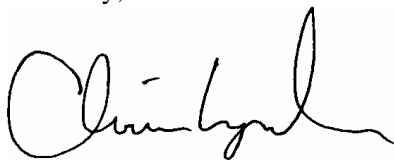
While a small percentage of the public may seek out research results in a central repository, a much more substantial number learn of medical research from private and electronic media. The *Journal*, for example, works with authors and the media to make sure that the final version of a research report, along with commissioned contextual pieces, are provided to the media in a coordinated fashion. These time-tested procedures provide sufficient time for the media to undertake the reporting and analysis required to produce accurate reports for the general public. If the NIH has a version of a research article weeks or months before it is published, will it assume responsibility for tracking and enforcing the media policies of various journals? If the research is politically charged or has implications for government policies, the NIH might find itself in the uncomfortable position of negotiating how the information becomes public.

As an interim step we propose the NIH work with publishers to provide access to the final version of a manuscript in a distributed manner. Rather than storing these manuscripts in a central repository the NIH could provide electronic links to the publisher's site to deliver the final copy of the manuscripts. This service could be enhanced by having publishers deliver full text content for users to search.

We ask you to consider whether we are "fixing a problem" that does not exist. In your view, if the problem of inadequate distribution of scientific information does exist, is it as significant as those who stand to benefit are depicting? And, finally, is this proposed solution a move forward or a step backwards in the ability of experts to mold research into knowledge for the public good? As our publishing colleagues recently stated in an open letter to you "no open, independent process of analysis has been undertaken to support the basis for the NIH's proposed policy actions at this juncture. Social arguments about hypothetical denial of access are rampant, but a dispassionate analysis of access denial and the consequences thereof have not been conducted, no doubt because there are no or very few real examples."

We urge you to work with the biomedical publishing community on experiments and more systematic analyses with the shared goal of providing evidence-based information access solutions that can truly improve healthcare delivery and outcomes. The Massachusetts Medical Society would welcome the opportunity to work with you and your representatives to further discuss these important issues and to forge a strategy to advance the goal of access without sacrificing the integrity of research.

Sincerely,



Christopher R. Lynch  
Vice President for Publishing