

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

Re: September 17, 2004 Federal Register Notice Titled, "Enhanced Public Access to NIH Research Information

Dear Sir or Madam:

The American College of Chest Physicians (ACCP) is a not-for-profit national medical specialty society representing more than 16,000 physicians and allied health professionals whose everyday practice involves treating diseases of the chest in the specialties of pulmonology, cardiology, thoracic and cardiovascular surgery, critical care medicine and anesthesiology. Our mission is to improve patient care through education. We do this in large measure through the publication of our respected, peer-reviewed medical journal, CHEST. Having reviewed the above-referenced notice published by NIH in the Federal Register ("Notice" or "Proposal"), we must respectfully oppose the NIH's Proposal on several grounds.

First, the Notice does not define a problem to be solved. Second, it raises more questions than it answers. Third, we believe it puts the Federal Government inappropriately close to the peer review process. Fourth, and undoubtedly most importantly, as best we can understand the Proposal, we believe it is likely to have the long term effect of undermining the quality of patient care. We would, of course, like the opportunity to meet with you at NIH to discuss our views in greater detail. Please call Michael Gaba at 202-419-2435 if you would like to do so.

The Notice Does Not Define a Problem to be Solved

The Notice states that NIH "plans to facilitate enhanced public access to NIH health-related research information." This statement implies that the public does not have sufficient access to medical peer-reviewed literature. But the notice neither defines such an access problem, nor articulates why the implied problem exists. Before NIH continues on its path towards implementation, we believe the agency must clearly define the problem it sees, why it believes the problem exists, and how its proposal solves the problem.

Our access policy for CHEST, which was established in 1999, is very much in line with what NIH appears to be proposing. We also believe that our policy is consistent with that of many other not-for-profit medical specialty society journals. From our perspective, the NIH "solution" appears to duplicate what exists in our community, and therefore, is unnecessary. It is, for all intents and purposes, already in place with most of the not-for-profit medical specialty society journals.

For example, all of our article abstracts (summaries) are available on-line immediately at no charge. The complete articles are available on-line 1 year after publication at no charge. If a non-subscriber would like the complete article within one year of publication, then that

individual or entity pays a modest fee of \$ 7.00. Further, it is worth noting that the annual subscription for CHEST is a very reasonable \$144 for individuals or \$186 for libraries per year. Given our current access policy and our nominal subscription rate, which we believe are consistent with the practices of other not-for-profit medical specialty-based journals, the ACCP does not believe a public access problem exists within the not-for-profit publishing community.

The Proposal Raises More Questions Than it Answers

The magnitude of what the agency appears to be recommending and the questions the Proposal raises also suggest that the U.S. Congress should be overseeing the development of this proposal before it is implemented. For instance, the Proposal indicates that NIH will provide federal funds to grantees to finance the peer review process. It is unclear, however, where these funds will come from, particularly in these difficult budgetary times. According to research done by Stanford University's University Press, approximately 65,000 NIH-funded articles appeared on PubMed in 2003. We are aware that at least one online Open Access journal charges authors \$1,500 per article to have them peer reviewed and published on its web site. Our experience and that of our colleagues in the not-for-profit publishing sector indicate that the actual costs associated with peer-review and publication for traditional print journals is approximately \$3,000 per article and upward. Given these figures, we estimate that NIH's Proposal would cost at least \$100 million per year, but more likely to \$200 million per year and upward.

Presuming new money is not available for this Proposal, it would appear that existing research funding would be the likely source to finance these proposed "author pays" fees. This would significantly and adversely impact the amount of NIH-funded research intended to improve public health. Diverting research funding for this exercise contradicts NIH's mission, which the ACCP fully supports, of "improving the health of Americans by conducting and funding biomedical research that will help prevent, detect, treat, and reduce the burdens of disease and disability."

If NIH were to implement this policy, it puts the Federal Government in the untenable position of having to divert research funding to commit to the peer-review function on an annual basis. When funding is constrained, it seems to us that there would be a natural pressure or temptation to squeeze the per grant resources available for peer-review. It strikes us that for these reasons, and others to be discussed below, the Federal Government should not inject itself into the peer-review process, in effect supplanting a private enterprise, which has functioned effectively when left to market forces.

The Federal Government Should Not Have a Financial Role in the Peer Review Process

We do not believe it is appropriate for the Federal government to insert itself in the peer review process of privately operated medical journals. CHEST, as do most, if not all, respected peer reviewed medical journals, abides by the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*, updated in November 2003 by the International Committee of Medical Journal Editors (ICMJE). The ICMJE requirements embrace the long established principle of peer review, that "[u]nbiased, independent, critical assessment is an intrinsic part of all scholarly work, including the scientific

process." (emphasis supplied) And with respect to conflicts of interest, which we must always strongly guard against, the ICMJE says, "[e]ditors may choose not to consider an article if a sponsor has asserted control over the authors' right to publish." This reference to "sponsors" includes commercial firms, private foundations, and government. Our view is that if the government sponsor funds the peer-review function, which is essential to publication, the ability of the journal and its editorial staff to maintain control over publication decisions could be compromised.

While we recognize that the Proposal is couched in terms of a "request" from NIH to its grantees, we are greatly concerned that this is a first step towards government encroachment upon the authors' right to publish. If the government inserts itself in the peer-review process, it could undermine the critical independent foundation upon which that process is built. Absent independent review, the value and quality of the medical literature could decline and not serve its purpose: to improve the health of Americans. And given its proposed role in the funding of the peer-review process, the government could very well stifle the publication of the same research it funds. In effect, the NIH could become a censor of medical literature. This is a "slippery slope" upon which the NIH should not venture. If it does, it should only do so with great care and oversight from Congress.

An Adverse Impact on the Patients we Serve

Most importantly, we believe NIH's Proposal will have the direct opposite effect of what is intended. Patient care is likely to suffer because the independence of the peer-review process will deteriorate, resulting in lower quality, less rigorous research results being reported. It is important to note that the ACCP, as a not-for-profit medical specialty society, as distinguished from the for-profit publishers, redirects the revenue it generates from CHEST subscriptions and advertising back into educational programs for its members to make them better doctors to improve the health of their patients. Our motivation is not to generate profit for shareholders, but rather to educate our more than 16,000 members to improve the quality of health care they provide.

Our patient-focused mission to health care is in synchronicity with the NIH. But we respectfully disagree with the agency's Proposal to achieve our common mission for a healthier America.

We thank you for the opportunity to submit these comments and look forward to working with the NIH to continue to improve the health of our citizenry. As mentioned above, we would welcome the opportunity to meet with you at NIH to discuss our views in greater detail. Please call Michael Gaba at 202-419-2435 if you would like to do so.

Respectfully submitted,

Richard S. Irwin, MD, FCCP
President

cc: The Honorable Arlen Specter
The Honorable Tom Harkin
The Honorable Ralph Regula
The Honorable David Obey
The Honorable Judd Gregg
The Honorable Edward Kennedy
The Honorable Joe Barton
The Honorable John Dingell
The Honorable Michael Bilirakis
The Honorable Sherrod Brown

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