November 16, 2004

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

Re: Comments from Health Affairs on the Proposal of the National Institutes of Health for
issued September 3, 2004

Dear Dr. Zerhouni:

We are pleased to have this opportunity to comment on the proposal of the National Institute of
Health (NIH) put forth on September 3, 2004, to enhance public access to NIH-funded research.

Agree with goal; concerns with proposal

Health Affairs, as the leading journal of health policy, sees its primary mission as one and the
same with that proposed by the NIH: that is, to increase the visibility and usefulness of top-
quality research so that it may inform efforts to improve health care systems both in the United
States and around the world. Health Affairs has been published since 1981 by the not-for-profit
organization, Project HOPE, a leader in international health education. I have served as its
Founder Editor since the journal’s inception, and my goal has been to provide a nonpartisan
forum for rigorous and timely policy research and debate on the nation’s most pressing health
care concerns. Health Affairs is now the number-one-ranked journal in the field, based on our
“impact factor” as measured by the Institute for Scientific Information.

While we share the goal of enhanced public access, we have concerns about aspects of the NIH
proposal’s concepts and implementation, which we discuss in detail here. Our primary concern is
whether the proposal may disproportionately affect the small, nonprofit journals that play a large
role in disseminating some of the nation’s top research for its most effective use. We would be very supportive of nonpartisan research into this question.

Overall, we ask that the NIH consider building more flexibility into its proposal to allow for the vast diversity among journals. The size of journal, frequency of publication, percentage of NIH-funded research published, and nonprofit status all have bearing on the ability of a journal to recoup its publication expenses if asked to make NIH-funded research papers free after six months.

We know from our experience at Health Affairs that most of the expense of a journal is in its labor. Our labor costs include: (1) seeking out new papers on the most timely issues of the day; (2) encouraging health care leaders to write Perspectives on the effects of new research or policy proposals, or interviewing such leaders, including yourself, as a means of getting these important views into the broader research and policy community; (3) reviewing papers internally; (4) managing the external peer review process; (5) working closely with authors to revise papers (something we spend a great deal of effort on to help researchers from a multitude of disciplines write for a policymaking audience); (6) careful, detailed editing for content, errors, and readability (so strongly do we believe in the “translational” role of our journal that we have been cited numerous times for our readability and have become the “most-read” health care journal on Capitol Hill); (7) formatting the content for both print and Web; (8) maintaining highly searchable and research-friendly Web site and archives in perpetuity, including continual technology upgrades; and (9) promoting the research widely to interested health professional and policy-making audiences, as well as to the lay reader via extensive media promotion. All of these efforts are costly but are critical components of getting the research read and used by as wide an audience as possible.

As a nonprofit journal, we have developed a business model that combines foundation grants and subscription revenues to support a break-even operation with a large amount of free access to journal content. However, our timetable and model for free access publishing does not match that proposed by the NIH. Our concern is what effect moving to the NIH model would have on our
ability to earn subscription revenue to support the wide range of activities involved in publishing a journal such as *Health Affairs*.

We believe that it is important for all stakeholders to reach a better understanding of this proposal’s effects—both in reaching the NIH’s goals and in avoiding unintended consequences that may have a deleterious impact on the future of scholarly research peer review and dissemination.

Our specific concerns are as follows:

**Potential for unintended negative effects on free-access publishing.** *Health Affairs* has a hybrid publishing model that already supports a great deal of free access to content. We strongly believe in making research content widely available and have joined with fifty-nine publishers as an original signatory to the DC Principles for Free Access to Science.

- About 25% of our most timely papers are published online-only as “Web Exclusives” and are free to all upon publication.
- Our entire archive of articles are available in full text online. Subscribers have access to the entire archive. Any nonsubscriber may access any article free after thirty-six months and may view individual articles that are not yet free access at a rate of $12.95 per article. We have waived this fee in cases of demonstrated need.
- Since November 2003 we have offered free online access to the journal to researchers in more than 100 low-income nations.
- We offer free access subscriptions to those who truly cannot afford to pay. We also provide complimentary copies of specific issues to thousands of key stakeholders on particular health care topics in an effort to contribute to the development of sound health policymaking.
- With our new subscription site license model, students and faculty at universities have site-wide online access to the journal under one low-cost subscription. This model has been so successful in opening up journal access on campuses that we now see single
Universities downloading thousands of articles a month from the journal—something that was never possible in the days of print.

- We offer free electronic interlibrary loan to aid those institutions that have not subscribed to the journal.
- As part of our move to HighWire Press in November 2003, we now offer free full-text reference linking to Health Affairs articles that are cited in any of the more than 700 journals hosted by HighWire. This feature greatly aids the researcher in following a trail of journal articles.
- All abstracts of Health Affairs articles are available free to all online and are indexed in MEDLINE, which is accessible via the NIH's PubMed Web site.
- Over the past year our online access has increased so dramatically that Web usage has more than quadrupled in one year.

While only 11% of Health Affairs papers are NIH-funded, fully one-third of the research we publish has funding from the U.S. Department of Health and Human Services. And virtually all of the research has funding from either a private foundation or public agency. Our concern, and that of many journals, is that the NIH, as the leading funder of health care research, is setting a closely watched precedent that will be emulated not only by other government funders but by private-sector funders as well. Indeed, the Wellcome Trust has announced its intention to implement a similar plan. If a large percentage of the papers we published were required to be available free after six months, this in combination with our current extensive free-access policies would almost certainly affect our ability to support the journal with subscription revenue. We would need to rethink our current free-access model at potential detriment to the policy-making community.

We would like to see the NIH encourage publishers' efforts that are already under way to increase access to research, instead of pushing all journals into a "one-size-fits-all" model. We believe that a quadrupling of Web usage in one year shows success in making research highly accessible and usable.
Risk of six-month access window for smaller journals. As the NIH, and potentially other funders, request free public access to their funded research, journals such as *Health Affairs* may find subscription funding erode as readers decide to wait six months to read articles when they are free. This may not be a problem for weekly or monthly publications; however, it is a greater concern for quarterly and bimonthly journals such as *Health Affairs*.

While the open-access “author-pays” model of raising publication revenue bears monitoring and evaluating, for *Health Affairs*, we believe that a key strength of our long-standing subscription model is that it spreads the cost of research dissemination not only among the research community that created and funded the research, but also to those organizations that may monetarily benefit from the research and can afford to pay for it. We have an extremely diverse audience of health care industry leaders, consultants, lobbyists, lawyers, investment analysts, and health benefits advisers who we believe should share in the cost of research dissemination, in addition to the more traditional academic research audience and government health policy-making audience. In addition, our current subscription model is actually less expensive for universities and other research funders than the author-pays model. A university-wide subscription to *Health Affairs* is less than one-quarter the cost to publish one paper in a PLoS journal.

*We would rather see the NIH focus its effort in a more targeted way on helping the particular audiences that cannot afford to pay for access to the research, instead of taking a blanket approach of a six-month free-access window for all NIH-funded research. The subscription model has the economic benefit of distributing costs widely. We believe that it is a viable financing mechanism for research dissemination, and it is in the best interest of the taxpayer and research community to share this dissemination expense with all those who benefit from and can afford to pay for access to the research. To this end, we ask that the NIH allow some flexibility on the six-month free-access window, especially to assist less frequently published journals in maintaining their subscription models.*
**Other ways to harness the power of the Web for NIH goals.**

The NIH has stated three objectives for its proposal:

1. Facilitate public access to NIH-related health research information.
2. Establish a fully searchable digital archive of NIH-funded research findings.
3. Improve the NIH’s ability to manage its research portfolio.

To this end, the NIH proposal requests that its research grantees deposit in PubMedCentral an electronic copy of the author’s final version of a manuscript accepted for publication in peer-reviewed journals (not the edited and corrected article as ultimately published). This “submission of the electronic versions of final manuscripts will be monitored as part of the annual grant progress review and close-out process,” according to the notices posted in the *Federal Register* and the *NIH Guide to Grants and Contracts*. The manuscript would become publicly available after six months.

Under the proposal, PubMedCentral, which was established as an open-access repository in 2000, would need to receive and prepare for posting some 60,000 – 65,000 manuscripts per year from individual researchers. Cost estimates for scaling PMC to handle such an endeavor and to improve its searching and retrieving functionality vary widely.

To fulfill the NIH’s laudable goals of access, searchability, and portfolio management, we believe that there are less costly, less centralized ways of harnessing the power of the Web. We ask that the NIH consider using a distributive model of archiving that builds on the linking power of the Web rather than building up PubMedCentral as a centralized archive. Under such a model, journals would continue to provide abstracts of all articles published to PubMed at publication, along with links to the final version of the article on the publisher’s site (as part of a program called “LinkOuts”). The advantages of such a model include:

- *Referring the public to the final published version of a research article, complete with extensive edits and corrections.* This would minimize the confusion of having several
versions of the research publicly available. And in the case of the clinical literature, this would minimize the potential public health problems of dosing errors or inaccuracies.

- **Providing searchable access to the full range of research, not just that funded by the NIH.** Currently MEDLINE/PubMed indexes abstracts of about 5,000 journals; about two-thirds of those participate in the LinkOut program. All research articles from these journals are indexed in MEDLINE, not just the 10% that are NIH-funded.

- **Providing the public with links to additional supplemental material related to the published research.** Such supplemental material may include additional data tables, further explanation of methodology, published corrections to the literature, and public comment on the research in the form of e-Letters.

- **Leveraging the sizeable investment publishers have already spent and are continuing to spend on improving the searchability and stability of online content.** If there are concerns about longevity of publishers’ Web sites, there could be a designated set of “approved” archives such as the one we use at Stanford University (HighWire Press, which was established in 1995 and is currently the largest free-access biomedical archive in existence). This would help avoid duplication of effort and taxpayer expense in creating highly searchable, interlinked archives to best serve the needs of the research community at large.

**Summary**

In sum, we believe that the NIH proposal, while well-intentioned, raises a number of concerns that bear closer evaluation before implementation.

(1) Will the proposal truly increase access for those most in need of free access to health care research, without jeopardizing scientific publishing and visibility of the research — especially for research currently published in smaller, nonprofit journals? We would support closer examination of this question by a nonpartisan research group, such as the GAO, prior to implementation of the proposal.

(2) Would the NIH consider allowing flexibility on the six-month access window to reduce the potential harm for smaller, less frequently published journals?
(3) Would the NIH consider using a distributive model of archiving that builds on the linking power of the Web rather than building up PubMedCentral as a centralized archive?

We greatly appreciate the opportunity to provide comments on the NIH proposal. We stand ready to answer any questions you may have about our suggestions for adding flexibility to the proposal and to build on the sizeable investment in research dissemination already under way in the publishing sphere. Ultimately, we wish to fulfill our mission of continuing to disseminate and increase access to the nation's health policy research.

Sincerely,

John K. Iglehart
Founding Editor
*Health Affairs*
Member, Institute of Medicine, The National Academies

Fitzhugh Mullan, MD
Contributing Editor, *Health Affairs*
Assistant Surgeon General, (Ret.)
Member, Institute of Medicine, The National Academies

Gail R. Wilensky, Ph.D.
Senior Fellow, Project HOPE
Former Administrator, Health Care Financing Administration
Member, Institute of Medicine, The National Academies