



August 23, 2004

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

Dear Dr. Zerhouni:

We write this open letter to you jointly on behalf of publishers and professional societies within several organizations: The Professional and Scholarly Publishing Division (www.pspcentral.org) of the Association of American Publishers (AAP/PSP; www.publishers.org), the American Medical Publishers Association (AMPA; www.ampaonline.org) and the DC Principles Coalition (www.dcpinciples.org). Our diverse memberships encompass the majority of the nation's leading journal publishers in biomedicine. Included among our members are preeminent medical and scientific society publishers that have announced their commitment to providing free access and wide dissemination of published research findings via the *Washington DC Principles for Free Access to Science*. Those publishers agree to work in partnership with scholarly communities "to ensure that these communities are sustained, science is advanced, research meets the highest standards and patient care is enhanced with accurate and timely information."¹ Many *DC Principles* adherents also are member societies of the Federation for American Societies for Experimental Biology (FASEB). We understand FASEB President, Paul Kincade recently sent you a letter communicating his concerns, which we share.

From your remarks during the July 28 meeting with an ad hoc group of scientific, technical, and medical (STM) publisher representatives convened by your staff, we understand that the National Institutes of Health, in its role as both a major US research center and granting agency, is on the cusp of proposing radical new policy with respect to the publication of NIH funded research. We were only made aware in mid-July of the US House Appropriations Subcommittee report language requesting that the NIH report to Congress by December, 2004 regarding a requested policy that NIH deposit, archive, and disseminate full-text research articles for studies describing the outcome of NIH-funded research. We have been assured by Congressman Ernest Istook's office that the House report language (not yet considered by the US Senate) was meant to be suggestive, and not prescriptive, and

¹ The *DC Principles* were put forward to provide what has been called the needed "middle ground" in the increasingly heated debate between those who advocate immediate unfettered online access to medical and scientific research findings and advocates of the established journal publishing system. The *DC Principles* counter the claims that publishers' practices hinder the public's ability to access published scientific research.

was intended to foster a process of consultation by the NIH with all stakeholders before any actual policy guidelines are put forward. From your remarks during our meeting, we were surprised to learn that the House report language was itself “inspired by the NIH”, and that you have been considering for some time the NIH’s position regarding so-called “open access” publishing models, albeit without apparent input from the broader international STM publishing community.

As the July 28 meeting was called in haste and was our first opportunity to air only briefly some of our concerns, we are alarmed that NIH appears to be rushing to judgement on its policy (possibly including announcement soon in the *Federal Register*) without sufficient advance consultation with key stakeholders, and without full evaluation of the potential impact its decision could have on the very fabric of scientific communication. We urge you to act now to engage leaders within the STM publishing community in an ongoing dialog, in the hope that we might find common ground. We respectfully request that you take this approach now, as we think our guidance would be helpful in advance of your announcing any draft policy for open comment. Should Congress indeed request your policy recommendation by December, 2004, then we stand ready to work with you to achieve that date (which we suggest would be the more appropriate timeframe for announcement in the *Federal Register*).

We understand your forthcoming policy to be driven by two motivations: 1) that the NIH itself should have an easy means to identify publications that result from NIH-funded research, and 2) that US taxpayers should have access to the results of government funded work. The solution you seem to favor is the establishment of PubMedCentral as a central institutional repository at the National Library of Medicine, with mandated deposit (presumably incumbent upon NIH grantee authors themselves) upon acceptance of their manuscripts for publication after journal peer review. PubMedCentral would undertake to manage the process of manuscript deposit and hosting (presumably including any standardized formatting and tagging to enable search and retrieval) and would make deposited versions of the manuscripts openly available via the internet, either at a specified interval after journal publication (e.g. a timeframe as short as 6 months) or immediately upon deposit in those instances where journal publication charges are paid by authors who have NIH grant funds. It is our understanding that the policy you are contemplating would continue to allow (non-US government employee) authors to assign copyright in their work to publishers.

We wish to arrange for a small delegation of our representatives to meet with you at the earliest opportunity, so that we may pursue the following concerns we share. There are other operational and practical issues that we sensed the NIH has not yet considered, that we feel also warrant careful discussion in advance of your issuing any policy recommendations for public comment.

- 1. We object to the notion that government intervention in scientific publishing is warranted, and believe that any policy that would mandate the deposition of scientific publications into a central, government-operated repository to be an inappropriate intrusion on the legitimate business interests of the private sector.**² 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. Moreover, economic arguments that focus on historical list prices for print subscriptions to journals, rather than the negotiated cost of access by consortia, do not

²We believe that a competitive international marketplace, free from subsidies or interventions that may confer market advantage or distort competition, must determine which business models and which publishers are best equipped to stay apace with the increasing demand for information exchange. In a diverse marketplace, open-access ventures are a valuable stimulus for all publishers to improve the services they offer. This is the nature of competition, which we unreservedly support and believe best serves the interests of the scientific, technical, and medical communities.

reflect the reality of the last five years. We are greatly troubled that either NIH policy, or a Congressional mandate (or both) may be used effectively to constrain the intellectual property rights of (non-US government employee) authors who are now unfettered in their freedom to transfer their copyright or assign exclusive publishing rights when publishing in any journal and with any publisher of their choosing. That such a move might be taken by the US government or one of its agencies, acting without any justification via evidentiary findings via an open process of analysis and debate, is alarming and without precedent in our industry. It is a clear instance of government interference with the interests of free enterprise, whereby both commercial and not-for-profit entities now compete openly in the more than \$8 billion international marketplace for STM information. A mandated repository also raises the specter of government encroachment on (including potential censorship of) scholarly discourse and academic freedom.

- 2. Alternatives to a mandated central government-run repository should be considered.** If permanent access to NIH-funded research is a concern for your agency, alternatives to your mandating compliance with an expanded PubMedCentral as the NIH's own central repository are numerous. The NIH need not mount a new central archive at taxpayer expense, but could rely instead on a distributed aggregation model, such as that undertaken successfully by more than 600 STM member publishers of *CrossRef* (www.crossref.org), a not-for profit network founded on publisher collaboration, with a mandate to make reference linking throughout the scholarly literature efficient and reliable.³ Given the adoption of the Digital Object Identifier (DOI) by virtually all major scientific and medical publishers, a linking strategy that would leverage the capabilities of the DOI as a permanent identifier, and also employ *CrossRef* as a linking backbone merits consideration by the NIH as a more cost-effective and scalable solution that should be explored as an alternative to the NLM's own PubMedCentral. A cross-linking approach also would enable each publisher to exercise appropriate control over versions, branding, and external web linking to its copyrighted content--none of which is enabled or protected if web traffic were instead diverted to article content made freely available via PubMedCentral. (We hasten to note that *CrossRef* itself imposes no policies regarding access to full-text content; rather, it enables a flexible range of access options, as determined by each publisher.) We also question whether the NIH considered other options, such as authors with extramural NIH funding depositing their work via society, publisher, or institution-based repositories, or the establishment of multiple "dark" deposit archives for failsafe preservation, or other strategies for distributed archiving efforts, as typified by the Stanford Library LOCKSS project (<http://lockss.stanford.edu/>). If so, why were these options rejected? Although no budget projections have been put forward to date, PubMedCentral, if expanded as outlined to serve as a central open access repository for all NIH-funded research, would no doubt prove to be both cumbersome and costly to manage and maintain at US taxpayer expense—to the detriment of research funding.
- 3. Requiring NIH-funded authors to deposit their accepted manuscripts in a central repository also has the potential to compromise the integrity of the scientific record.** Practical issues, such as measures to verify that the document deposited by each author represents the final accepted version, controls to ensure the fidelity of information, steps to correct clinical errors in dosage, nomenclature, etc.(problems effectively addressed by the publisher during copyediting) would need to be managed by the NIH—adding redundancy and cost. Presently, most publishers arrange to assign unique DOIs to article content made available on their web sites, and use those unique identifiers to establish linking relationships between pre- and post-publication versions of a work. If authors deposit their accepted manuscripts separately for processing and hosting on PubMedCentral the ability to distinguish among versions could be compromised or lost, article content could be modified inappropriately, and inaccurate medical information might be disseminated in error.

³ *CrossRef* currently provides a citation linking backbone for nearly 12 million records via the implementation of the Digital Object Identifier (DOI), which serves as an Open URL-compliant web standard that lowers the barriers to content discovery and accessibility, and provides for permanence of digital content.

4. **We challenge the premise that because US taxpayers fund research, then the articles that result from all such funded studies, publishable only after the painstaking and costly process of peer review, should be made openly available by a US government agency to the world as a public good.** Many professional and scholarly publishers have US-based operations, and are both employers and taxpayers. They have made sustained investments in technology and added-value features to build their assets. At what economic detriment to them – and further cost to US taxpayers – would your plan be accomplished? To base policy on such a notion would be a terrible precedent for any US government agency to establish. While it may be appropriate that NIH policy address the need for standards to assure the digital archival preservation of NIH-funded research reports, we do not feel that the government has any justification for usurping the current role of publishers by itself openly disseminating the same peer-reviewed information that journals are now in the business of communicating.

5. **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--thus far a monolithic and unproven economic model of publishing. In putting its “thumb on the scale” in this way, the government would be introducing bias into scientific publishing and would risk diminishing, not enhancing, the value that NIH-sponsored biomedical research now delivers to society.** In its present incarnation, the “author pays” model of open access publishing has critical shortcomings, and has not yet been proven to be acceptable to the majority of scientific authors, even when offered to them on an optional basis. There is as yet no evidence to support the purported merits of author-paid alternative publishing models. Their financial viability and sustainability remains unproven, and their “vanity press” nature has been criticized as being inconsistent with the value delivered to science and society by established “reader pays” models, which support selectivity and encourage editorial rigor. Even the highest article fees charged by open access publishers today cover only a fraction of the estimated total costs to publish an article of the quality, accessibility, and functionality that researchers are used to today. Remaining costs, estimated to be several billion dollars for the STM publishing industry globally, would have to be covered by foundation, university, and government subsidies. Also, for universal access to be a reality, publishers must continue to make information available in multiple media formats. Print is used by many researchers around the world, and by global citizens who are the beneficiaries of scientific and medical research. At present, the user-pays model supports the cost of dual electronic and print publication. . An author-pays model of open access publishing could well add an additional cost burden to funding agencies like the NIH, or research investigators and their institutions, that will detract from funds that would be better spent on research itself. Those corporations and institutions that are research users but not producers, who now pay for that access and thereby defray some of the costs of publication, will get a free ride on the backs of research-producing institutions and countries.

6. **Publishers stand ready to work with the NIH and relevant patient organizations to explore new ways to enable consumer access to technical information presented in the right context, and to measure its effectiveness. Furthermore, the assertion that access to the medical literature is unduly restricted is a red herring.** The last decade in STM publishing—the context in which the open access debate has emerged—has been marked by technological innovation that is far from over. The increase in use of the literature by researchers has undergone phenomenal growth, as online full text has become ubiquitous. Contrary to the assertions by proponents of open access, the *status quo* of access to published medical advances is not impeded by the subscription model; rather, all business models are in a state of flux as publishers experiment with expanding access by a variety of means. The published literature is routinely and readily available to all who need and want it, whether through paper subscription, online licenses, electronic pay-per-view, individual document delivery, free interlibrary loan, paid sponsorship or

(in the developing world) philanthropic donation of online access⁴. Today, more people have more access to more information than ever before in history. Many biomedical publishers (including but not limited to those that adhere voluntarily to the *DC Principles*) already have made considerable amounts of original research content openly available via the web. Most leading journals now make available immediately selected articles deemed to be of major importance to public health. Depending on their economic requirements, many publications also open their archival content within 12-24 months (some even less); those that do not typically offer individual articles for a nominal pay-per-view transactional fee. For the lay reader who is unprepared to pay for access, there are well-established provisions for access to the technical literature that involves no compensation to the publisher (e.g., interlibrary loan).

7. **We urge you to work with the biomedical publishing community on experiments and more systematic analyses, with the shared goal of providing selective, evidence-based information access solutions that can truly improve healthcare delivery and outcomes. This approach is preferable to the NIH unilaterally mandating a “one size fits all” policy for immediate or 6-month delayed public access to all original research studies supported by NIH-funds.** We are not aware of any systematic studies that have demonstrated improved patient treatment outcomes as a result of access to original articles by the healthcare consumer. Would the NIH assert that all pharmaceuticals, medical devices, patents, and other discoveries that result from NIH-funded research be made freely available, and that the NIH itself set up a mechanism to allow the general public to select from among them at will? We think not---and therefore question why the NIH thinks technical medical information should be offered up to the public in so cavalier a fashion, with the risk also of undermining the economic foundation on which it rests. It is debatable whether members of the general public can actually benefit from reading the original research literature, as its arcane and specialized reporting is intended primarily for other researchers, and many findings are not relevant for immediate clinical application. Recognizing this, many consumer-oriented medical publishers, professional medical societies and associations, and major patient advocacy organizations, now expend considerable effort to generate educational medical content in aid of the lay healthcare consumer. (The NIH’s own Medline Plus is an example of this sort of information service.) As an alternative to PubMedCentral as a central repository for disseminating any and all research studies, unfiltered, to the general public, we believe there are opportunities to work in tandem with those who serve the consumer health marketplace to facilitate access to original research results---presenting such information in an understandable context for the “expert patient”. For example, criteria and standards for publisher-enabled linking of published original articles reporting NIH-sponsored research outcomes to other educational/interpretive content, or to database registries of important clinical trials would be areas of fruitful collaboration, particularly if combined with criteria for assessing impact on medical outcomes.
8. **We wish to clarify whether your policy will be an “unfunded mandate” or will carry with it additional funding to support scientific communication.** If funding is to be infused, we feel strongly that NIH research investigator grants should not earmark funds that would favor any given publishing model, nor introduce provisions, guidelines, or strictures that would be fundamentally anti-competitive in nature. NIH policy should not restrict an author’s freedom to publish with (and transfer copyright to) any publisher of his or her own choosing. We also note that the possible requirement that payment of publication charges with NIH funds would necessitate immediate open access to the article via PubMedCentral would be particularly deleterious for those journals (many of them society-owned) that now rely on such revenues to offset costs that otherwise would be borne by subscribers. Indeed, “open access by mandate” carries with it the risk of unintended consequences, such as the demise of scholarly and medical

⁴ Online access is provided *gratis* to research institutions throughout the developing world by publisher participants in the WHO/HINARI initiative (www.healthinternet.org)

societies that rely on the income from their journals to pay for their operations and activities, which add great value in their disciplines.

- 9. We would welcome a dialog with the NIH regarding the governance and ongoing operation of PubMedCentral , which to date has essentially served as a full-text repository for the selected benefit of only those publishers willing to make their content freely available via open access.**⁵ Given the important role seen for PubMedCentral, which lacks diverse publisher representation, we ask for a more consultative process in its planning and governance that would involve broader input from the STM publishing community at large, not just from open access publishing advocates. At present, publisher participation in PubMedCentral as a full-text repository is voluntary, and certainly should remain so. However, we feel that the appropriateness of the NIH's continued use of US taxpayer dollars in operating PubMedCentral is questionable, given its current scope and focus. PubMedCentral is arguably an example of governmental activity that has been duplicating and competing with the efforts of the private sector. That said, the voluntary uptake and use of PubMedCentral as a full-text repository by the international STM publishing community (including major medical societies) has been modest at best---confined largely to those willing to experiment with open access models, or leverage its capabilities for their own business interests. In large part, this is because the majority of STM publishers, both commercial and not-for-profit, remain concerned about inherent bias in PubMedCentral's governance structure and policy agenda, both of which overtly favor those publishers willing to adhere to "open access doctrine". (We should note that this is in sharp contrast to the widespread publisher cooperation achieved by *CrossRef* (www.crossref.org) and between publishers and the NIH's own *PubMed* and *Medline* abstracting and indexing services, which are perceived to present a more level playing field, and to complement the business interests of publishers.)

As you assess the concerns we have raised above, we share also a comment from Richard Horton, editor of *The Lancet*, taken from a personal communication:

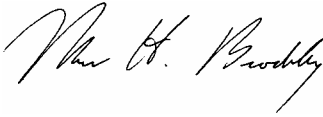
"Open access (to the knowledge of the great nineteenth-century teachers of medicine and surgery, for which they charged students vast amounts of money to hear) was the very reason why Thomas Wakley launched the The Lancet in 1823 – but at a small cost to the user. As a physician and editor, I want to see stronger medical and research cultures within our society. For all those who take part in the debate about open access, I would urge that they answer this one question: what is the system of publication that best serves the person on whom the entire edifice of medical publishing depends – the patient?...The sum total of the responses, will, I suspect, give a complex picture, one that is unlikely to fully support either user-pays or author-pays models. But the debate will force important further questions about the assumptions on which all models are based. Existing user-pays approaches have critical benefits to both science and society."

We would welcome the opportunity for an ongoing dialog to discuss these important and complex public policy issues with you and your colleagues from the NIH as you formulate your draft

⁵ The NIH's efforts with PubMedCentral (established during Dr. Varmus's tenure at the NIH and now supported within the National Library of Medicine) originated in confluence with a protest movement by principals of what emerged as the Public Library of Science, who asked scientists to boycott those publishers that would not allow unrestricted free access to their journal articles six months after publication. PubMedCentral, housed at the NIH campus in the NLM's National Center for Biotechnology Information, has sought to be a voluntary, comprehensive full-text depository archive of the biomedical literature, yet has not achieved that goal. It essentially acts as an open access distributor for a small fraction of the biomedical literature—a cadre of approximately 80 journals, plus an additional 60 or so new titles launched by BioMedCentral (a commercial entity that is pursuing an author/sponsor-paid business model, and in doing so operates in close collaboration with PubMedCentral). This activity seems not to be in keeping with its proper role as a government-funded entity, as its operation and its governance are biased in favor of those with a particular business model, as evidenced by the composition of its Advisory Board since its inception.

publishing policy. We will be in touch with your office to request a time for a delegation of our representatives to meet with you.

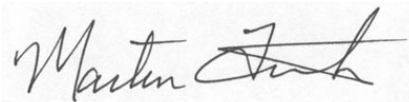
Sincerely,



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Honorable Thomas Harkin (D-IA), Ranking Minority Member, US Senate Appropriations Subcommittee on Labor, HHS, and Education

Honorable Ralph Regula (R-OH), Chairman, US House of Representatives Appropriations Subcommittee on Labor, HHS, and Education

Honorable Ernest Istook (R-OK), Chairman, US House of Representatives Appropriations Subcommittee on Transportation, Treasury and Independent Agencies

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