Association of American Publishers, Inc.
www.publishers.org

50 F Street, NW, 4th Floor
Washington, D.C. 20001
Telephone: (202) 347-3375
Fax: (202) 347-3690

aap

National Institutes of Health
Office of Extramural Research
Bethesda, Maryland 20892

May 30, 2008

RE: Request for Information – NIH Public Access Policy

To Whom It May Concern:

I write on behalf of the Professional & Scholarly Publishing Division of the Association of American Publishers to submit the two attached documents for the record in response to the Request for Information (RFI) that was published by NIH at pages 16881-16895 of the Notice section in the Federal Register of March 31, 2008 (Vol.73, No.62).

This cover letter, along with the two referenced attached documents, is being sent to NIH via email to PublicAccessComments@NIH.gov, as directed by Neil M. Thakur, Special Assistant to the NIH Deputy Director for Extramural Research, in a May 29-30 email exchange with James F. Segroves of the law firm of Proskauer Rose LLP, based on Mr. Thakur's confirmation that the PDF format used for all three documents is not suitable for posting to NIH through the submission template made available for that purpose at http://publicaccess.nih.gov/comments2/comments.htm.

The two attached documents submitted for the RFI record are, respectively:

A letter addressed to me by Jon A. Baumgarten of Proskauer Rose LLP, dated May 30, 2008, in response to my request for an analysis of the relationship between the NIH Final Policy on Public Access and certain aspects of U.S. and international copyright law; and,

A letter addressed to Dr. Elias Zerhouni by the Chair and Vice Chair of the Executive Council of the Professional & Scholarly Publishing Division of the Association of American Publishers, dated March 17, 2008, which originally was timely submitted to NIH in response to its request for comments on the implementation of the NIH Public Access Policy pursuant to NOT-OD-08-057 (March 7, 2008).

Both of these documents raise important issues regarding compliance with the statutory proviso that Congress included in Division G, Title II, Section 218 of the Consolidated Appropriations Act, 2008 (Public Law 110-161) to make sure that "the NIH shall implement the public access policy in a manner consistent with copyright law."

We appreciate the opportunity to provide these materials to NIH and thank you for ensuring that they will become part of the record in response to the RFI.

Sincerely,

Allan Adler
Vice President for Legal & Government Affairs

71 Fifth Avenue
New York, NY 10003-3004
Tel (212) 255-0200
Fax: (212) 255-7007
www.publishers.org
www.pspcentral.org

March 17, 2008

Elias A. Zerhouni, M.D., Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
Transmitted via email to PublicAccess@nih.gov

RE: NIH Notice on Public Meeting: Seeking Comments on the Implementation of the NIH Public Access Policy
NOT-OD-08-057 (March 7, 2008)

Dear Dr. Zerhouni:

We are writing on behalf of the Professional and Scholarly Publishing Division (PSP) of the Association of American Publishers (AAP) to relay important practical concerns that have been expressed by many of our members regarding implementation of the "NIH Revised Policy on Enhancing Public Access to Archived Publications Resulting From NIH-Funded Research." These members of the PSP publish the vast majority of materials produced and used by scholars and professionals in science, medicine, technology, business, law, and the humanities, and they employ tens of thousands across the United States.

While the PSP supports the principle of public access to science, we have significant concerns about aspects of the NIH public access policy's implementation that we believe may have unintended negative consequences for all stakeholders in the scientific research community, including the broader public.

We note that many of our concerns as scholarly publishers stem from the manner in which NIH and staff responsible for PubMed Central have implemented the public access policy, by taking liberties with copyrighted content in a fashion that competes with the activities of independent publishers and that undermines their rights in copyright. Specifically, by reprocessing and enriching manuscript submissions and expropriating publishers' value-added investments in peer-reviewed content, NIH is creating enhanced, derivative publications that go beyond the congressional mandate of posting researchers' documents that report on the results of federally funded research. Rather than just posting what it receives, be it an author's version (after peer review) or a publisher's submission (in a PDF or other fixed format), NIH has embarked upon XML-reformatting and tagging procedures to create alternative versions of published works that, when made freely available, substitute for the definitive articles in which publishers have already invested. In effect, NIH is entering the publishing business (and enabling other international mirror locations of its database to do so as well) by creating these enhanced derivative versions. As a result, the integrity of the scientific literature is compromised.

Below we have grouped our comments by topic and included relevant questions, focusing on the (A) importance of consultation with publishers as to the effective implementation of the new public access policy; (B) need for real safeguards to ensure meaningful protection of publisher copyright as Congress intends; and (C) development of best practices to ensure that the public access policy meets its stated objectives.

A. Consultation with Publishers: NIH must ensure that there is a formal and ongoing consultative mechanism between NIH and publishers in which NIH and publishers commit to attaining a balanced implementation of the policy that achieves the public access objectives without negative impact on peer review publishing. The Senate committee report (110-107) to the FY08 LHHS Appropriations bill directed NIH to seek publisher input to ensure that publishers' copyright protections are maintained under the new policy.

1. How has the policy that NIH announced on January 11, 2008, only weeks after the legislation was signed into law, incorporated publisher input, and how will NIH incorporate the concerns of publishers as it moves forward?

2. We would like to work with NIH toward an effective and fair implementation of this policy. We propose that a task force or advisory group, co-chaired by NIH and publisher-designated representatives, be vested with the requisite authority and responsibility to propose procedures for implementation of the policy mandate.

3. In the NIH Notice of Jan 11, NIH notes that "institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Policy." Why would NIH place grantees in the position of negotiating with publishers in the complex world of copyright law? Why not reach agreements with publishers regarding payment for their journal articles, so as to remove from authors the administrative or financial burden of compliance with the policy?

4. The policy will have a negative impact on publishers, many of whom are small professional societies, because with their copyrighted material freely available on PubMed Central, subscription or other article-related revenues may well decline. What is NIH's plan to track possible harm to publishers, especially small societies? If harm is found, how does NIH plan to remedy it? Does NIH understand the basis for publishers' concern about such possible harm and its impact on publishers' willingness to invest in promoting the integrity and widespread availability of the scientific literature?

5. What are NIH expectations of its grantees with regard to ensuring that PMC postings of material will not diminish the rights that are acquired by publishers in that material, the value of the publishers' added contributions, and the interests of authors?

6. Will NIH provide publishers with detailed and robust PMC usage statistics that will enable them to assess the impact of PMC usage on their subscriptions? It is not clear from current NIH policies and procedures how publishers may obtain detailed and robust PMC usage statistics that will enable them to assess the impact of PMC usage on their own web traffic and subscription or other article-related income.

B. Proper Protection of Copyright: NIH must develop specific safeguards to ensure that day-to-day implementation of the public access policy respects the basic principles embodied in copyright and not undermine these rights that provide incentives for publishers to invest in the peer-reviewing, publishing, distribution, and archiving of scientific articles.

1. How will NIH ensure that any revisions to copyrighted materials such as reformatting, enhancing, linking, or otherwise changing the articles do not undermine the rights, added value and interests referred to above?

2. How will the policy protect against distribution of copyrighted materials to other sites around the world besides PubMed Central?

3. How will NIH address possible objections or concerns from copyright owners who do not assent to the public posting of their material on PubMed Central and its related international sites, or who have concerns about the enforcement of copyright located on and delivered from those sites?

4. Publishers recoup the expense of peer review, production, and distribution by several means, including commercial sales. When copyrighted articles are freely available online, their commercial value can be eroded. How will NIH ensure that the policy will protect publishers' intellectual property assets, retaining the commercial value of the copyrighted articles?

5. Recognizing publishers' copyright and investments in peer review and publishing, does NIH plan to supplement its grant funds to sponsor public access to the manuscripts? If yes, how will such funds be identified in the grant, and what has NIH budgeted per year for such incremental costs?

6. How will NIH ensure that the articles on PubMed Central meet with publisher requirements, such as the access-control period, and that the policy actually applies to the articles that NIH is posting?

7. How will NIH prevent piracy of the articles from PubMed? Will NIH monitor for mass downloading of posted articles by single users? How will NIH work with publishers in the event that copyrighted articles are pirated from PubMed Central? If NIH finds that articles have been subject to piracy, how will NIH notify the publisher and provide any information NIH may have about the infringer? Will NIH provide for review and revision of the public access policy if piracy occurs from PubMed Central or the other international repositories connected with PMC?

8. How will NIH ensure that the articles on PMC maintain the publisher's branding, and if applicable, the corresponding disclaimers and notices so that publishers can preserve their brand assets and manage their liability appropriately?

C. Good Faith Implementation: NIH must agree to adopt and develop certain best practices to ensure that the public access policy meets and adheres to its stated objectives.

1. Since PMC will compete with publishers' own websites as more PMC content overlaps with content on publishers' sites, how will NIH maintain the primacy of the publishers' websites and ensure that the manuscript on PMC does not displace or act as a substitute for the final published journal article, i.e., the authoritative version of record, which resides on a publisher's site? Will NIH work with publishers to ensure that readers know and are directed to where the final published versions can be obtained?

2. Many publishers provide free access to authors' manuscripts or final published articles twelve months after publication or even sooner. NIH does not consider this access compliant with the NIH

policy. Would NIH consider including author manuscripts only in its administrative database and archive, while providing public access via display only through publisher sites? If not, what is the rationale for maintaining an unedited manuscript for public consumption if the final, authoritative version has been made available for free access on the publisher's site?

3. What will NIH do in cases of noncompliance with its policy guidelines? What action will be taken when a grantee's article is published, but NIH is not provided with the peer-reviewed manuscript? What actions will be taken against noncompliant grantees when they apply for future NIH grants?

4. How does NIH anticipate securing and sustaining a source of funding to maintain the database of articles that will accumulate over time, including costs to migrate to new platforms? Under the new policy, US taxpayers will be funding public access to science to any person anywhere in the world with Internet access. Has the NIH considered the ramifications of providing such international access, and how this might affect national security or other US government trade regulations?

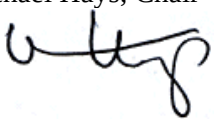
We look forward to the public meeting at NIH on March 20 and the upcoming RFI proceedings, but considering the far-reaching implications of the substantial change in the NIH public access policy, we urge HHS and NIH to do a full Notice and Comment Rulemaking. We believe that the public and the publishing community should be given an opportunity to comment on the content of the new policy before it goes into effect. We urge HHS and NIH to hold off on implementing the policy until after the Notice and Comment proceedings have been completed.

We also look forward to a more formal process for working closely with NIH to implement the new public access policy.

Thank you for the opportunity to communicate our views.

Sincerely yours,

Michael Hays, Chair



F. Hill Slowinski, Vice-Chair

Executive Council, Professional and Scholarly Publishing Division
Association of American Publishers (AAP/PSP)

PROSKAUER ROSE LLP

1001 Pennsylvania Ave., NW, Ste 400S
Washington DC 20004-2505
Telephone 202.416.6800
Fax 202.416.6899

BOCA RATON
BOSTON
CHICAGO
LONDON
LOS ANGELES
NEWARK
NEW ORLEANS
NEW YORK
PARIS
SAO PAULO

Jon A. Baumgarten
Member of the Firm

Direct Dial 202.416.6810
jabaumgarten@proskauer.com

May 30, 2008

Allan Robert Adler, Esq.
Vice President for Legal & Government Affairs
Association of American Publishers
50 F Street, NW, 4th Floor
Washington, D.C. 20001-1530

Dear Mr. Adler:

This is in response to your request for a succinct description of my views with respect to the relationship between the NIH Final Policy on Public Access[1] ("Final Policy"), on the one hand, and the U.S. Copyright Act,[2] other copyright laws, the Berne Convention for the Protection of Literary and Artistic Works,[3] and the Agreement on Trade Related Aspects of Intellectual Property ("TRIPS") on the other.

For the reasons set forth in the remainder of this letter, I believe that the Final Policy raises serious questions and substantial doubt pertaining to its consistency with copyright law and to the United States' compliance with its obligations under the Berne Convention and TRIPS; and may well provide a precedent and template for other countries to depart from important standards of international copyright protection and trade.

[1] Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, NOT-OD-08-033 (National Institutes of Health; Released January 11, 2008; Effective April 7, 2008) (hereinafter "NIH Notice").

[2] 17 U.S.C. § 101 *et seq.*

[3] Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, revised, Paris, July 24, 1971, 25 U.S.T. 1341.

I. General

A. Breadth and Impact of the Final Policy

NIH has very recently characterized the Final Policy as involving "a small strand of the worldwide rights" comprised in the copyright initially held by authors and transferred to publishers.[4] However, the Final Policy requires the deposit and reproduction of peer reviewed journal articles on a public Website -- PubMed Central -- accessible and downloadable in full text, by any one, at any time, anywhere, for the very same informative purpose served by journal publication, and any other user motivation, throughout this country and the world (including but not limited to mirrored sites), a short time after journal publication. In both substance and effect, at the expiration of just 12 months from publication, the Final Policy (a) forcibly, broadly and dramatically excises from the "bundle or rights" of the copyright owner the most fundamental rights of reproduction, public display, and public dissemination inhering in copyright;[5] and (b) in competition with the publisher, provides the work to an unlimited, worldwide, public. The NIH's belated characterization is not apt.

B. Government Action

The Final Policy is U.S. Government action; hence it directly implicates the international obligations of this country, perceptions of its actions and U.S. leadership in international copyright and trade affairs and forums, and the responsibilities of agencies and legislators. Contrary to the assertions of some, it is far from merely a "matter of contract" and should not be immunized from legal, international, and policy scrutiny by convenient rubric and faulty analogy. Moreover, the Final Policy is focused and targeted by government on every instance of a specific category of work: publisher peer-reviewed, scientific writings pertaining to NIH funded research. It is promulgated by an agency responsible for the greatest portion of pertinent funding in the world, and hence reaches and impairs the copyright in a vast swath of published scientific journal literature.[6]

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[4] *Public Access Frequently Asked Questions* F.6, http://publicaccess.nih.gov/FAQ.htm#content (hereinafter "NIH FAQ").

[5] 17 U.S.C. § 106(1), (3), (4) & (5). Because NIH may introduce changes, tags, edits or the like, the right to make derivative works under section 106(2) is implicated as well.

[6] *See, e.g.*, NIH FAQ F.4 ("We estimate that there are approximately 80,000 papers published each year that arise from NIH funds.").

In sum, the Final Policy bears all the hallmarks of, and is indistinguishable in purpose or effect from, legislation that would amend the Copyright Act to either truncate the term of public exposure rights in scientific journal articles to no more than twelve months from publication, or create a wholesale exception from copyright in such works for unconsented posting on a publicly accessible government Website.[7] That would certainly be questionable domestic policy; in addition, for the reasons given in Part III of this letter it would appear to violate this country's international obligations and claims to world leadership in intellectual property and trade affairs.

C. Mandatory Condition

The Final Policy is emphatically and unabashedly mandatory[8] and coercive.[9] It is imposed by government on initial copyright owners (authors), and sought to be imposed on their transferees without real assent. Non-compliance has meaningful adverse consequences.[10] In the past, NIH very explicitly and repeatedly justified an earlier PubMed Central deposit policy on the grounds it was voluntary;[11] yet it has simply and conveniently ignored those considerations in its adoption of the unwavering, mandatory rule.[12] This alone is likely a fatal flaw in both the rule's adoption[13] and implementation.[14]

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[7] Indeed, NIH contends that the Final Policy is a direct application of legislation, the 2008 Consolidated Appropriations Act. *E.g.*, NIH FAQ A.1; NIH Notice. Of course, that legislation conditioned NIH's actions on "consisten[cy] with copyright law," a condition the Final Policy may fail to fulfill. *See infra* Part II. In any event, the treaty obligations of the United States can certainly not be avoided by simply recasting or even implementing legislation as regulation, or cloaking offending legislation or regulation in pervasive "contract" terms. *See infra* Part III.

[8] *See* HHS/NIH Request for Information: NIH Public Access Policy, 73 Fed. Reg. 16,881, 16,881 col. 3 (Mar. 31, 2008) (". . . as of April 7, 2008 applicable manuscripts arising from NIH funds must be submitted to PubMed Central . . . .") (hereinafter "RFI"); NIH FAQ B.8, C.11.

[9] *E.g.*, RFI at 16,881 col. 3 ("As of May 25, 2008, NIH applications, proposals, and progress reports must include the PMC reference number when citing a manuscript that falls under the policy."); NIH FAQ B.9 ("Non compliance will be addressed administratively, and may prevent or delay awarding of funds"); NIH FAQ C.1(III) and C.10 ("Enforcement actions" for non-compliance, including *preclusion* "of future awards for specified periods").

[10] *See id.*; *see also* Preprint article from ARL: A Bimonthly Report, n.2508 (June 2008) (delayed funding for non-compliance "can cause significant problems for an institution[al grantee] in terms of resource planning and allocation").

[11] *See, e.g.*, RFI, 73 Fed. Reg. at 16,881 col. 3, 16,882 col. 1, 16,885 col. 1, 16,888 col. 1, 16,889 col. 2, 16,890 col. 2.

[12] For example, NIH had asserted a rulemaking was not needed because "the [former] Policy does not require investigators to do anything other than what the current rules require," RFI, 73 Fed. Reg. at 16,889 col. 2, yet the Final Policy clearly does impose a new requirement, but a rulemaking was not held prior to adoption of the Final Policy and new requirement, and a formal Petition for Rulemaking timely filed by several publishers was not replied to. *See also infra* Part II.A. Even more fundamentally, NIH earlier stated that "The [former] Policy explicitly

II. Copyright Law

NIH apparently relies on Division G, Title 2, Section 218 of the 2008 Consolidated Appropriations Act (herein "section 218") as grounds for the Final Policy. However, various activities of NIH and fostered by it -- individually and in combination,[15] including reformatting, editing, and mirroring -- appear to go beyond Congress's limited reference to PubMed Central posting and to exceed that authority.[16] In any event, that section, as well as general principles of governance and regulatory responsibility, requires that the Final Policy be "consistent with

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recognizes and *upholds the principles of copyright [because] [f]irst, submission of the final manuscripts is voluntary rather than mandatory*." RFI, 73 Fed. Reg. at 16,888 col. 1. Additionally, NIH had earlier argued that "the [former] Policy does not interfere with [Fifth Amendment concerns and Exec Order 12630] as authors and institutions will be voluntarily submitting copies of final manuscripts to NIH . . . ," *id.* at 16,890 col. 2, but appears to have ignored its elimination of that safeguard under the Final Policy.

Although Fifth Amendment considerations as such are outside the scope of this letter, I note that NIH's prior recognition of that issue was incomplete. In addition to proprietary interests of grantees in what NIH described as "the funding recipient's ability to assert a copyright . . . ," publishers themselves have a valuable and likely cognizable property interest in their investments and expectations underlying the peer review process itself. Courts have acknowledged, for example, a very wide scope of potential Fifth Amendment property interests, including those pertaining to intangibles. *See generally Adams v. United States*, 391 F.3d 1212 (Fed. Cir. 2004), *cert. denied*, 126 S. Ct. 330 (2005). Even if the Final Policy does not completely deprive publishers of the ability to exploit some uses of peer-reviewed articles posted on PubMed Central, that does not negate a prohibited "taking." *Cf. Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825 (1987) (public easement). It is clear that NIH is demanding deposit of the peer-reviewed manuscript reflecting that investment and will not settle for less, *see* NIH Notice; and it is equally clear that NIH has otherwise acknowledged the importance of that added value. *E.g.*, 73 Fed. Reg. at 16,885 col. 3 ("enormous value and critical role" of peer-reviewed journals and limitation of PubMed Central to peer-reviewed articles). It is difficult to understand, and NIH has apparently not explained, how either its Final Policy or implementing "license" from *grantees* can reach out and take that *publisher* added value, at least without compensating the publisher.

[13] *See infra* Part II.A (APA violation).

[14] *See infra* Part II.C (section 201(e) of Copyright Act).

[15] The sum total of the planned activities of NIH under the Final Policy can aptly be described as *publishing*, not simply archiving, in competition with commercial, society, and other not for profit private sector entities. This is particularly relevant to, among other legal and policy issues, the apparent failure of the Policy to comply with U.S. obligations under the Berne Convention and TRIPS Agreement. *See infra* Part III.B.

[16] For this reason, NIH is wrong in its conclusion that a rulemaking was not required prior to adoption of the Final Policy because it was simply and directly reflecting section 218. The addition of a *proviso* by Congress to section 218, which NIH has left in doubtful compliance at best, and the conventional expectations of Congress with respect to agency action, also undermine this assertion. *See infra* Part II.A.

copyright law." NIH[17] and some of its supporters[18] assert that the policy is compliant with copyright law solely because it rests on a "license" extracted by or on behalf of the agency from authors or institutional grantees of NIH funding. However, for the reasons next given, I believe that justification is quite suspect and, at the very least, should not be asserted or taken on the mere face of it as the basis for a general rule.

A. Rulemaking Required

To begin with, it is likely that the Final Policy itself has been improperly adopted, and is therefore contrary to law, and hence it and its implementations, by license or otherwise, should have no effect. This is because the Final Policy is a "legislative rule" and neither NIH nor HHS has conducted a notice and comment rulemaking as required by the Administrative Procedures Act to be undertaken and completed prior to its adoption.[19] The Final Policy is a legislative rule (and not a mere interpretive rule or general statement of policy) principally because it amends a prior HHS regulation[20] by explicitly extending its reach to the peer-reviewed version of articles,[21] and because it is now mandatory in nature.[22] In the latter connection, it is quite

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[17] *E.g.*, NIH FAQ F.6. However, NIH may be hedging its bet on the "contract" rationale. Although it earlier disavowed reliance on the fair use doctrine to cover PubMed Central posting, *see* RFI, 73 Fed. Reg. at 16,889 col. 2, its current FAQ says: "United States and/or foreign copyright laws protect most of the papers on PMC; PMC provides access to them at no cost, much like a library does, under the principles of Fair Use." NIH FAQ F.2. The placement of the second comma here certainly suggests that NIH believes such posting to be "consistent with copyright" because of fair use, not contract. I do not believe that regular, unauthorized PMC posting of complete, current, final peer-reviewed manuscripts of published journal articles for unconstrained, worldwide, public access can or will qualify as fair use. *Accord* Michael W. Carroll, *Complying with the National Institutes of Health Public Access Policy: Copyright Considerations and Options*, at 4, SPARC/Science Commons/ARL (Feb. 2008) (hereinafter "Carroll"). If that is the, or an alternative, justification for the Final Policy, it utterly fails to meet the proviso to section 218; moreover, its application to justify the Final Policy under the Berne Convention and TRIPS would be untenable and seriously disruptive. (If the fair use reference was intended only to refer to "libraries," the FAQ still fundamentally errs in its analogy, and vastly overstates the fair use defense of libraries.)

[18] *See* Carroll, *supra* note 17; *see also* Preprint Article from ARL, *supra* note 10.

[19] *See* 5 U.S.C. § 553(d); *see also* 70 Fed. Reg. 6,891, 6,898 (Feb. 9, 2005) (NIH concession that it does not have general rulemaking authority).

[20] 45 C.F.R. § 74.36(a).

[21] The HHS regulation currently provides that the federal government only retains a right to reproduce, publish or otherwise use a work that was "developed, or for which ownership was purchased, under an award." The Final Policy, in contrast, effectively amends and expands the regulation such that NIH seeks to retain rights in works that were not "developed, or for which ownership was purchased, under an award" i.e., the peer-reviewed version of the article (and, arguably the author manuscript – as opposed to research and progress reports – even before peer review, and perhaps "graphics and supplemental materials that are associated with the article" but subject to the Final Policy). *See Am. Mining Congress v. Mine & Safety Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993) (agency cannot, through an interpretive rule, contradict or amend a prior legislative rule). Although it has not done so, NIH

pertinent that NIH specifically claimed earlier that its prior "voluntary" policy was not subject to rulemaking precisely because it was not mandatory.[23]

It is quite clear that NIH's current proceeding, undertaken after adoption of the Final Policy, is not a substitute for and cannot justify the failure of a pre-adoption notice and comment rulemaking. Publishers and the public are entitled to careful agency consideration of a full administrative record made on a specific proposal *before* the agency makes up its mind.[24]

B. Publishers' Acquired Rights

As noted above, NIH now asserts that the Final Policy rests on a minor diminishing of the rights that might be transferred by funded researchers in articles to publishers; yet this characterization is untenable. As explained above, that policy, and its associated license, do not merely encumber the copyright acquired by publishers; they denude it. That impact certainly cannot be dismissed as legally "de minimis" or unworthy of consideration.

C. Rule against Transfers that are not "Voluntary"

Additionally, the Final Policy appears to fly in the face of both the spirit and letter of section 201(e) of the Copyright Act. That section provides:

> (e) Involuntary Transfer. -- When an individual author's ownership of a copyright, or of any of the exclusive rights under a copyright, has not previously been transferred voluntarily by that individual author, no action by any governmental body or other official or organization purporting to seize, expropriate, transfer or exercise rights of ownership with respect to the copyright or any of the exclusive rights under a copyright, shall be given effect under this title, except as provided under Title 11 [the bankruptcy laws].[25]

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might assert that the Final Policy is merely an interpretation of the HHS regulation. However, NIH is not authorized to "interpret" the HHS regulation when NIH's interpretation has the effect of amending it.

[22] *See Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382-83 (D.C. Cir. 2002) (agency action a legislative rule and not a "general statement of policy" if it is binding on the public); *see also supra* note 16.

[23] *See supra* note 12.

[24] *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979).

[25] 17 U.S.C. § 201(e).

Although this section was initially motivated by the potential acts of foreign governments with respect to U.S. copyrights of their national authors,[26] the exception for U.S. bankruptcy law and other factors make quite clear it is designed to be binding on U.S. government agencies as well.

Because the Final Policy is, by NIH's own terms, adamantly "mandatory" and coercive,[27] has been explicitly distinguished by NIH from its prior "voluntary" policy,[28] forcibly extracts rights from the author prior to their later transfer to a publisher, and then mandates the NIH's exercise of such rights, it appears on its face to be in conflict with the proscription in Section 201(e), and hence the "license" should not be "given effect" under the copyright law.

I recognize that in *Herbert v. United States*,[29] a Claims Court judge seemed to conclude that section 201(e) was not in conflict with a broad HHS "Rights in Data" procurement license incorporated in a particular government contract, because it found -- apparently without analysis -- that the license was not "involuntary" since the plaintiff's putative employer could in theory have declined to enter into the contract. The record in that case, however, appears quite different from that here, and the opinion somewhat puzzling. The "individual author" who asserted protection of section 201(e) was not even a party to the contract; his putative employer concluded it. (Of course, if the latter were an employer, the former, the plaintiff, would not be an "author" at all under copyright work for hire principles.) There was not even a threshold showing, as is apparent here, that the pertinent agency itself considered the regulation to be mandatory, across the board and in explicit contrast to an earlier "voluntary" policy. There was no showing of the breadth of impact on copyright rights generally even approximating that which may be applicable here; and no exploration whatsoever of the practical consequences of non-compliance or considerations pertaining to a potential individual or institutional grantees' disavowal of grants by an agency with overwhelming influence on grantees and applicants. The court did not explain why, if the individual author was not an employee -- a decision it expressly declined to make on summary judgment -- the section would not apply notwithstanding the individual author's complete non-participation in the agreement which was assented to only by the putative employer, or how that could be "voluntary" acceptance of the license by the "individual author" himself so as to eliminate section 201(e) in that case. To the extent that the court's focus on voluntariness can even be understood in that context, it adopted an arguably superficial or artificial interpretation of "involuntary" which, if followed without further

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[26] *See generally* Jon A. Baumgarten, US - USSR Copyright Relations Under The Universal Copyright Convention, at 4-5, 40-44, 114-115 (PLI Copyright Practice Handbook 1973) (hereinafter "Baumgarten"); *see also* 119 Cong. Rec. S5613-14 (daily ed. Mar. 26, 1973) (Sen. McClellan).

[27] *See supra* notes 8 and 9.

[28] *See supra* notes 8 and 11.

[29] 32 Fed. Cl. 293 (Ct. Fed. Cl. 1994).

examination, will certainly undermine the purpose behind the legislation, even in its original motivation.[30]

A rather different approach to section 201(e) was taken by a District Court judge in *Association of American Medical Colleges v. Carey*.[31] Plaintiff argued that the forced public exposure of plaintiff's copyrighted secure tests under New York State's "truth in testing law" violated section 201(e)'s prohibition on involuntary seizure of copyright. In principle, the court might have characterized the disclosure as a "voluntary" price paid by plaintiff to do business in New York much as the *Herbert* court may have been characterizing the putative employer's acceptance of the license in its contract or NIH might seek to characterize a researcher's acceptance of a PubMed Central posting license in its grant; but *it did not do that*. Although the court found for plaintiff on Federal preemption grounds, and so did not definitively pass upon this section 201(e) claim, it observed that "the unambiguous language of this provision supports plaintiff's position that a state, as any other individual, may not abrogate a copyright owner's federally protected rights."[32] (The Court of Appeals remanded the preemption holding for further analysis and substituted temporary relief for the permanent injunction below, but did not explore the section 201(e) issue.)

D. Jointly Authored Works

An additional defect in the Final Policy's consistency with copyright and its reliance on an extracted license pertains to papers written jointly by NIH research funded authors with others who are not so funded and hence not subject to the license. NIH asserts or implies that its "license" from one author is sufficient in those circumstances.[33] Although U.S. copyright law generally (and unlike foreign copyright laws, *see* Part II.E) permits unilateral licensing by one joint owner without the consent of others, there is a long standing exception for licenses that

[30] For example, the Soviet dissidents whose potential fate originally motivated this provision (that is, it was initiated by concern that the Soviet government would expropriate their U.S. copyrights and seek to enjoin publication of dissident works in the United States, *see* Baumgarten, *supra* note 26) did have a range of alternatives that could have avoided seizure or exercise of their copyright rights in the U.S. abroad -- such as avoiding foreign publication, facing various manifestations of official displeasure, perhaps only forfeiting royalties, and others. *See id.* at 4-5.

[31] 728 F. Supp. 873 (N.D.N.Y. 1990), *rev'd and remanded on other grounds sub nom., Ass'n of Am. Med. Colleges v. Cuomo*, 928 F.2d 519 (2d Cir. 1991).

[32] *Id.* at 884 n.7.

[33] NIH FAQ C.1; *see also* NIH FAQ B.3. Carroll is quite explicit on this point. *See supra* note 17, at 9. Because the licensing coauthor derives a substantial economic benefit from the grant, even application of the U.S. general rule, which commonly requires an equitable sharing of revenues from unilateral licensing, raises questions as well.

substantially injure the copyright.[34] In light of the potential impact of the NIH Final Policy described above, this exception may well apply.[35]

E. Foreign Copyright Laws

Especially given today's environment, in which foreign markets and copyright laws have been of fundamental Congressional and Executive Branch concern, there is no real reason to conclude that section 218 of the 2008 Consolidated Appropriations Act was concerned only with consistency with U.S. copyright law, and cavalierly ignored, or invited disregard for, the laws of other countries where posting on PubMed Central (and on mirrored sites fostered by NIH) would result in display, downloading, or other "copyright acts" abroad. Fundamental principles of international copyright would leave the legitimacy of those acts to be determined by the laws of the jurisdictions where they occurred, which can differ in pertinent respects from U.S. law.[36] Even apart from the "consistent with copyright law" proviso to section 218, responsible regulatory action that, like the Final Policy, clearly has and is specifically designed and intended to have international impact must take into account and should seek to comply with the laws of those countries.[37]

III. The Berne Convention and TRIPS

Article 2(1) of the Berne Convention and Article 9(1) of TRIPS require members to protect "literary and artistic works" that is, "all productions in the literary, scientific, and artistic domain . . . ." There is no doubt that scientific journal articles and manuscripts are entitled to

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[34] *Maurel v. Smith*, 271 F. 211 (2d Cir. 1921).

[35] Courts have concluded that overly broad licenses by a joint author can result in destruction of the copyright. *E.g.*, *Shapiro, Bernstein & Co. v. Jerry Vogel Music Co.*, 73 F. Supp. 165 (S.D.N.Y. 1947) (noting impact of new and emerging technologies); *Crosney v. Edward Small Prods.*, 52 F. Supp. 559 (S.D.N.Y. 1942).

[36] 4 Melville B. Nimmer & David Nimmer, NIMMER ON COPYRIGHT § 17.

[37] It is the case that public access issues related to government funding are being explored in countries outside the United States. But that is why this is not the time for the United States to impose and justify a policy that is prejudicial to a working and highly publicly beneficial private sector publishing model, and that will likely significantly distort international standards of copyright and trade. My understanding is that publishers' experience with non-U.S. research funding bodies in this environment shows that there are a real variety of models to accomplish the purpose of public access to publicly funded research; and that forcibly taking something quite close to the final version of an article as published at only 12 months and without adequate compensation directly to the publisher or respect for publisher policies, is not at all the only way to reach that objective or one necessarily endorsed as palatable by reasonable voices.

full Berne/TRIPS protection.[38] Article 2(4) of the Berne Convention does give member countries leeway in dealing with "*official texts* of a *legislative, administrative, and legal nature*" (emphasis added). However, this special "official texts" category certainly does not cover scientific journal articles and manuscripts, and neither Article 2(4) nor any other aspect of Berne or TRIPS permits special exceptions or limitations for works related to government funding that are produced by private authors and entities[39] (with the possible, here wholly inapplicable, exception of privately developed, government funded texts of codes and regulations that are later adopted into positive law).[40] The meaning of Article 2(4) is clear -- such works as involved in the Final Policy must be protected for the full Berne/TRIPS minimum period (far in excess of 12 months from publication);[41] and any limitations and exceptions to the exclusive rights of reproduction and public dissemination or display of such works are permissible only if meeting the standards of the well-known "three step test."

As noted in Part I.B of this letter, the Final Policy must be viewed as U.S. Government action and is indistinguishable from a legislative exception to copyright term and rights. Insofar as it will be seen to be a truncation of copyright term, it is not compliant with the treaties. Insofar as it is an exception from or limitation on rights, it must be measured against the important constraints of the "three step test." For the reasons given next, it is at least very doubtful that the Final Policy can pass that test.

The test requires that non-enumerated limitations and exceptions[42] on exclusive rights be -- in the words of TRIPS Article 13 -- "confined to [1] certain special cases which [2] do not conflict with a normal exploitation of the work and [3] do not unreasonably prejudice the legitimate interests of the rights holder" (numbering added). It is universally understood that the three conditions are

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[38] *See* 1 Sam Ricketson & Jane Ginsberg, INTERNATIONAL COPYRIGHT AND NEIGHBORING RIGHTS: THE BERNE CONVENTION AND BEYOND 406 (2005) ("written description of an experiment, process, device or the like") (hereinafter "Ricketson & Ginsberg"); *see also id.* at 413 ("technical and scientific" writings).

[39] This is similar to U.S. copyright law, under which works of officers and employees of the United States made in their official capacity are not protectable, but works made by others under U.S. government contract or grant are. *See* 17 U.S.C. §§ 105 and 101 (definition of "work of U.S. Government").

[40] *Cf.* Ricketson & Ginsberg, *supra* note 38, at 503 n.477.

[41] *See* Berne Convention Article 7(1); TRIPS Article 9.

[42] Because Article 2(4) of the Berne Convention does not apply, there is no enumerated (or "specific") limitation or exception based on the relationship of scientific articles to government funding. *See generally* Carlos M. Correa, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT ch. 5 (2007).

strictly cumulative, and *each criterion must be met.*[43] While there is some discussion of whether the third criterion under the Berne text contemplates impairment of the rights of an authors' transferee, such as a publisher,[44] that is academic here in light of TRIPS' explicit and intentional restatement of that standard to identify the interests of the "rights holder."

It appears that the Final Policy would likely *fail each one* of the three steps (though failure of *any one* would be enough to condemn the policy). More specifically:

A. "Certain Special Case": It is possible to *define* the works affected as only "peer reviewed articles or manuscripts reporting on NIH funded research," and so the situation is probably a "certain" one under the treaties.[45] However, that nominative categorization does not meet the first step; instead, it is generally understood that the exception itself must be "narrow in its scope and reach" in order to be a "special case."[46] For the reasons given in Part I.A of this letter, the extraordinary breadth of intrusion effected by the Final Policy -- reaching and severely limiting several of the most fundamental rights of copyright owners over a broad range of affected works -- would likely not pass muster as "narrow in scope and reach."

NIH has occasionally sought to justify the Final Policy on grounds of furthering medical research.[47] Assuming, for the purpose of this letter only, validity in that premise, it is clear that a

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[43] *E.g.*, World Trade Organization, Report of the Panel re United States - Section 110(5) of the US Copyright Act, WT/DS160/R para. 6.97 (June 15, 2000) ("The three conditions apply on a cumulative basis, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 13 exception being disallowed.") (hereinafter "Panel Report"); *see also* Ricketson & Ginsberg, *supra* note 38, at 763.

[44] Article 2(6) of the Berne Convention suggests that the third criterion can contemplate transferees of the author, since it provides that "protection shall operate for the benefit of the author and his successor in title." Some commentators take that position on that basis or otherwise. *But see* Ricketson & Ginsberg, *supra* note 38, at 774.

[45] *See* Panel Report para. 6.108 ("certain" means "clearly defined").

[46] *See* Panel Report para. 6.112; *see also id.* at 6.109; Ricketson & Ginsberg, *supra* note 38, at 764.

[47] *E.g.*, RFI, 73 Fed. Reg. at 16,884 col. 2, 16, 887 col. 2. Interestingly, NIH claims that its policy will promote "scientific progress," *id.* at 16, 885 col. 1, yet that is precisely a role played by private sector scientific publishers themselves (and potentially undermined by NIH) just as intended by the Constitutional underpinning of copyright law. *See Am. Geophysical Union v. Texaco Inc.*, 802 F. Supp 1, 4, 16, 27 (S.D.N.Y. 1992) (Leval, J.), *aff'd*, 630 F.2d 913 (2d Cir. 1994).

NIH's premise has been strongly contested by some participants in NIH proceedings who have argued, for example, that medical progress would be better served by NIH's focusing more funds on research then in duplicating private sector publishers' efforts.

"good" or "public" purpose alone is not sufficient to meet the first test -- the quantitative criterion must still be met.[48]

B. "Interference with Normal Exploitation": This step requires consideration of the exception as a matter of avoiding potential competition with authorized licensing or sale, etc. of the protected work.[49] Because non-consensual, mandatory posting of peer-reviewed manuscripts or articles would appear to unavoidably impair subscription revenues and publishers' own emerging or increasing Website and electronic exploitation of their journals[50]--to posit negligible effect from forcing publishers to "compete with free" versions of their works seems naïve at best -- the Final Policy should be seen to fail this step as well.

C. "Unreasonable Prejudice [to] Legitimate Interests of the Right Holder": Where there is "interference with normal exploitation," as discussed immediately above, there is no need to address this step.[51] It has been suggested, however, that the "interests" under this step may be broader than the strict revenue interests in copyright exploitation.[52] Publishers' general business interests in recouping, maintaining and expanding their investments in peer review, article selection, editing, formatting and the like, and choosing and varying suitable business models, may fall within this broader ambit, as may their stated concerns with piracy downstream from PubMed Central. Since the wording implies that a certain level of prejudice may be

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[48] *See generally* Ricketson & Ginsberg, *supra* note 38, at 764-767; Daniel J. Gervais, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 146 (2d ed. 2003). The commentators' debate is in part whether, assuming there is a sufficiently narrow impact, a good or public purpose must still be shown; and here I am questioning the "narrowness" of impact, not the purpose. Moreover, Article 8(1) of TRIPS makes it very explicit that "measures necessary to protect public health and nutrition [assuming, again, that the standard of objectivity and necessity might have some applicability here in principle] must be "consistent with the provisions of this agreement [i.e., including the three step test of TRIPS]."

[49] *E.g.*, Panel Report para. 6.183 ("We believe that an exception or limitation to an exclusive right in domestic legislation rises to the level of a conflict with normal exploitation of the work . . . if uses that in principle are covered by that right but exempted under the exception or limitation enter into economic competition with the ways that rights holders normally extract economic value from that right to the work . . . .").

[50] The WTO Panel noted that "normal exploitation in a marketplace may evolve as a result of technological developments;" and that "one way of measuring the normative connotation of normal exploitation is to consider, in addition to those forms of exploitation that currently generate significant to tangible revenue, those forms of exploitation which, with a certain degree of likelihood and plausibility, could acquire considerable economic or practical importance . . . ." Panel Report para. 6.187; 6.180.

[51] Ricketson & Ginsberg, *supra* note 38, at 773.

[52] Panel Report para. 6.223 ("interest may refer to a concern about potential detriment or advantage, and more generally to something that is of some importance to a natural or legal person. Accordingly [it] is not necessarily limited to actual or potential economic advantage or detriment.").

"reasonable," application of this step may be more open to dispute. However, the breadth of impact that publishers have asserted may follow from the appropriation of their peer-reviewed articles may well place the Final Policy beyond the pale of this criterion as well.[53]

As noted earlier, I do not believe that the Final Policy can be immunized from the three part test or treaty minimum terms simply on the grounds it is "a matter of contract." If that facile rationalization were to prevail, it would not be difficult to envisage other countries' attempts to manipulate such an approach toward broad and potentially devastating impact on protection of U.S. works abroad and the high level standards of protection that are needed to support common, multi-national intellectual property and trade objectives. For example, mandatory "licensing" and "contract" excisions of copyright protection could be artificially imposed at critical access points to accord the "benefit," if not of funding, then of reaching national markets, government supported or allied institutional customers, and government businesses and institutions -- notably including countries where government enterprise is more pervasive than in others -- and the fabric of years of valuable effort to enhance intellectual property and trade benefits not-so-slowly unwound and eroded.

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Please let me know if you have any questions regarding the foregoing. I understand that this letter may be submitted by you to the NIH and others.

Very truly yours,

Jon A. Baumgarten

JAB/clt

[53] *See* Gervais, *supra* note 48, at 150.