The American Physiological Society

9650 Rockville Pike Bethesda, MD 20814-3991

March 17, 2008

NIH Public Access Staff
National Institutes of Health
Transmitted via email to PublicAccessComments@nih.gov

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

To the National Institutes of Health:

These comments are submitted on behalf of the American Physiological Society (APS). In addition to its views on the policy implications of the NIH proposal, the APS is submitting a legal analysis jointly commissioned by the APS and the American Association of Immunologists (AAI). The legal analysis was originally submitted November 16, 2004, in response to NOT-OD-04-64 (September 3, 2004) and is being resubmitted at this time. In NOT-OD-05-022 (February 3, 2005), NIH dismissed several issues raised in our legal analysis by stating that the points were not relevant since the May 2, 2005 Public Access Plan was voluntary. With the release of NOT-OD-08-057, the NIH Public Access Policy is no longer voluntary, which now makes certain legal issues raised in the earlier analysis germane.

The APS/AAI legal analysis may be found as Attachment A.

Request for a Rulemaking

On March 7, 2008, NIH announced that it would conduct a public meeting on March 20, 2008, to discuss the agency's implementation of the Revised Policy. That notice also announced that NIH would publish a Request for Information (RFI) in the Federal Register during the month of March, and that NIH would respond to comments within 120 days after the close of a 60-day comment period. However, that notice states that the Revised Policy will nevertheless go into effect on April 7, 2008.

APS is pleased that NIH has chosen to solicit the public's views regarding the important issues raised by the Revised Policy and looks forward to participating in that process. We believe, however, that NIH's "regulate first, ask questions later" approach not only violates the letter of the Administrative Procedure Act (APA), but that it also violates the spirit of that statute.

The APA requires that regulated entities and the public be given an opportunity to comment on the content of a regulation before it goes into effect, absent emergency circumstances -- an exception that is not relevant here. The APS believes that NIH is obliged to engage in notice and comment rule-making since the courts have held that the failure to engage in notice-and-

comment rulemaking cannot be cured by an agency's acceptance of comments after the effective date of a legislative rule such as the Revised Policy. In other words, permitting the submission of views after the effective date of the policy is no substitute for the right of interested persons to make their views known to the agency in time to influence the rulemaking process in a meaningful way. Consequently, the APS respectfully requests that HHS and NIH stay the effective date of the Revised Policy and grant the rulemaking petition that was submitted to HHS on January 11, 2008 as soon as possible.

The NIH apparently recognized that it might have to comply with the APA in 2005. NOT-OD-05-022 stated:

> The Policy does not require investigators to do anything other than what the current rules require. While funding recipients may follow the Policy to fulfill some of their existing reporting requirements they need not do so and may continue to provide hard copies of publications.

Inasmuch as the April 2008 policy now mandates deposit of manuscripts, this removes any flexibility in terms of how to comply. Thus, it is our view that as a mandatory requirement, the proposed policy is a rule-making which means that APA notice and comment and other procedural requirements for final agency actions must be followed.

Recommendations

The APS supports the principle of public access to science but believes that the NIH plan is not the right approach because it is not a collaborative endeavor. The implementation of this policy will come at great cost to the NIH, the research community and the American taxpayer. It will also cause disproportionate harm to not-for-profit societies that publish high-quality journals containing a significant amount of NIH-funded research. This group includes many publishers who have been at the forefront of providing free public access from journal websites within 12 months after publication.

The APS believes that NIH could have achieved greater success 3 years ago had it enhanced the existing MedLine/PubMed web site to enable full text searches of articles on the journals' own websites. Such searches would yield links to finished articles on those websites rather than access to manuscripts as PMC now provides. A number of publishers were interested in this approach, which would have led to the development of a comprehensive search engine that would do for biomedical research what search engines such as Google and Yahoo do for the web as a whole. The APS urges NIH to revisit this approach because it has a number of advantages to all parties. For NIH, this arrangement would make it possible to search the text of all biomedical research articles and not just the 10% that are based on NIH-funded research. Journals, and especially high-quality journals that publish a significant proportion of NIH-funded research, would still be able to determine their own access policies within a 12-month window and based upon their own cost recovery requirements. Finally, and perhaps most importantly, instead of access to manuscripts, this would make it possible to locate the final copy-edited articles of record presented in context with links to related materials such as commentaries and corrections.

Specific Problems with the New Policy

1. **Incorrect terminology**

The policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) which states:

> *SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.*

The Public Access Frequently Asked Questions (FAQs) posted on January 11, 2008, has created confusion because it used the wrong terminology. In numerous places the document refers to journal articles rather than final peer-reviewed manuscripts as stated in the legislation. Specific instances where this occurs may be found in the answers to question 1 under General Information and questions #1 – 7 under Scope of the Policy.

The confusion caused by multiple references to journal articles may encourage investigators to submit final published article to PubMed Central in violation of revised copyright agreements made in good faith by publishers such as the APS that grant NIH funded authors the right to make their accepted manuscripts publicly accessible through PMC 12 months after publication. NIH clearly knows the difference between final peer-reviewed manuscript and the final published article as evidenced by the FAQ response provided under C ("How to Comply With the Policy - #5. What is the difference between a final peer-reviewed manuscript and a final published article?"). **All improper references to journal articles should be replaced immediately with correct references to final peer reviewed manuscripts. Moreover, NIH should draw attention to the correction and monitor information being disseminated by third parties to ensure that the misconception is not perpetuated.**

2. Scope of the Policy

The language in Section 218, PL 110-161 suggests that NIH-funded investigators must deposit every accepted manuscript into PMC whether or not the actual research reported in a given manuscript was supported by NIH. This is a significant issue for investigators who might receive funds from multiple sources including private sources. There is an implied threat that failure to do so might jeopardize future requests for NIH grant support. This requirement vastly expands NIH "ownership" of its grantees' work. The 2005 NIH policy focused solely on the research funded by NIH. **NIH must clarify the scope of the policy to ensure that investigators know with certainty which research manuscripts they must submit. Moreover, it should provide justification for its expansive claim to its grantees' works.**

The 2005 voluntary policy stated that it did "not apply to contributed book chapters, editorials, reviews, or conference proceedings." Rather, it applied "only to peer-reviewed research publications." This was consistent with statements Dr. Zerhouni made during an October 2004

meeting with publishers. During that meeting, Dr. Zerhouni encouraged publishers to maintain the subscription base of their journals by publishing reviews and other non-research materials. **The inclusion of reviews under the 2008 mandatory policy breaks Dr. Zerhouni's promise to publishers and will undermine the economic viability of these same society journals.**

The 2008 policy also threatens to exacerbate problems caused by NLM's flawed implementation of the 2005 policy. The policy that went into effect on May 2, 2005 clearly stated that it "focused on final peer-reviewed manuscripts and publications that result from research supported, in whole or in part, with direct costs from NIH." However, NLM failed to create a system that would screen out submissions that fell outside the scope of the policy. As a result, publishers had no choice but to police the site themselves and request removal of non-compliant articles one-by one in order to defend their legitimate copyright interests in those items.

Under the 2005 voluntary Policy, investigators only submitted 4% of the NIH-funded manuscripts, with publishers submitting another 20-25% of the eligible manuscripts. Under a mandatory Policy, the volume of investigator submitted manuscripts will increase dramatically and so will the burden on publishers to make sure that authors comply with the terms of their copyright agreements. **It is critically important for NIH to work with publishers to modify the NIH manuscript submission site to ensure that only manuscripts eligible for submission may be uploaded.** As a publisher, the APS is prepared to work with NIH to address these issues.

Another reason why non-compliant uploads may be expected to increase is confusion caused by NIH's failure to make a consistent distinction between peer-reviewed manuscripts and articles in its FAQ. It is therefore all the more urgent that NIH modify its submission site to prevent the upload of non-compliant articles. Absent such action, it is difficult for publishers to believe that the NIH has any meaningful interest in protecting publishers' copyright.

Publishers have asked NIH to help protect publishers' copyrights by creating a database of journal embargo periods as a means of assisting authors to comply. The request was denied because NIH did not want to influence the submission decisions of their investigators. There is a great tradition in scientific publishing that it is unethical for the funding agencies to influence where and how an article was published. However, NIH has now created a list of journals (http://publicaccess.nih.gov/submit_process_journals.htm) that submit articles directly to PubMed Central on behalf of authors. By providing the list, NIH may be perceived as encouraging authors to publish in a small subset of journals that have established a favorable relationship with the agency.

NLM's Mission

The preservation of the biomedical literature is a responsibility mandated in NLM's authorizing legislation, found at 42 U.S.C. 286(b)(1). While the NLM has done an excellent job of preserving the printed biomedical research literature going back to 1836, it has not devised a suitable plan to do so for digital content. The APS and other publishers have urged NIH to exercise its responsibility to preserve digital journal content in collaboration with journal publishers. Many publishers whose content will be subject to the new policy previously offered

to work with NLM to preserve the digital record by depositing the entire content of their journals for use within the NLM. NLM rejected this offer. Instead, the current plan will only preserve articles funded by the NIH, which comprise just 10% of the total biomedical literature.

Many publishers have expressed a willingness to work with NLM on digital preservation and would deposit both NIH and non-NIH funded content to create a digital archive that would fulfill many of the goals of the NIH Public Access Plan. The viability of the archive could be assured through its use on the NIH campus and within the NLM with the understanding that public access would be provided via a link to the publisher's online journal. In so doing, NIH would be able to preserve the scientific literature, maintain an archive for portfolio management, have the ability to search the entire scientific literature, and direct the public to free access available from the publishers. The maintenance of a complete archive by NLM would enable NIH to utilize it to set its research priorities, something that cannot be done with an archive that contains only 10% of the biomedical literature.

The APS as a scientific publisher

The American Physiological Society is a not-for-profit scholarly association founded in 1887 to promote the advancement of physiology. Today the Society has nearly 11,000 members who are scientists involved in physiological research and the teaching of physiology. APS members hold positions at colleges, universities, and medical schools and in industry, government, and independent research institutions. In the fulfillment of its mission, the Society publishes peer-reviewed journals; sponsors scientific meetings and conferences; and provides professional development opportunities for its members as well as educational and mentoring programs to identify, encourage, and train future physiologists. For its efforts in the latter areas, the APS was awarded the 2003 Presidential Award for Excellence in Science, Mathematics, and Engineering Mentoring.

The Society publishes 14 journals that provide venues where research findings are validated through peer review and disseminated to other scientists. In 2007, 8,710 manuscripts were submitted to APS journals for peer review, and 4,642 of those manuscripts were ultimately published. The Society's oldest journal is the *American Journal of Physiology*, which was founded in 1898, and its newest journal is *Physiological Genomics*, which was founded in 1999.

Thank you for considering the comments we have submitted on behalf of the American Physiological Society.

Sincerely,

Hannah V. Carey, Ph.D.
President, American Physiological Society

Martin Frank, Ph.D.
Executive Director, APS

Enclosure

ATTACHMENT A

Legal Analysis Prepared for the American Physiological Society and The American Association of Immunologists by Foley & Lardner LLP

FOLEY

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November 16, 2004

Via email to PublicAccess@nih.gov

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

Re: Notification Concerning Enhanced Access to National Institutes of Health (NIH) Research Information - Attachment A to Comments of The American Association of Immunologists and the American Physiological Society

To the National Institutes of Health:

Foley & Lardner LLP represents The American Association of Immunologists ("AAI") and the American Physiological Society ("APS") (jointly "the Associations"). This letter provides the comments of the Associations as to legal issues related to the notification published in the Federal Register titled "Enhanced Access to National Institutes of Health (NIH) Research Information" ("Notification"), 69 Fed. Reg. 56074 (Sept. 17, 2004).[1]

In the Notification, the National Institutes of Health ("NIH") announces a "plan" under which NIH would require NIH-sponsored grantees and their Principal Investigators ("PI") to submit to the National Library of Medicine ("NLM") manuscripts that have been peer-reviewed and accepted for publication, but not edited and prepared for publication, by professional

[1] Both AAI and APS are submitting separate comments on the public policy issues raised by NIH's plan. This letter is Attachment A to the respective individual comments of each and is incorporated by reference therein.

biomedical journals.[2] The effect of this requirement would be to populate the NLM's database, PubMed Central ("PMC"), permitting NLM to become a major repository, and effectively the predominant disseminator, of biomedical research information in the United States. As discussed below and in the Associations' separate comments addressing the public policy aspects of NIH's plan, the Associations, in their own right and on behalf of their members, and despite their long-standing support for the principle of public access, strongly oppose NIH's plan.

I. SUMMARY OF LEGAL OBJECTIONS TO NIH'S PLAN

- NIH's plan would infringe on the copyright interests of (a) federal grantees who author copyrighted articles based upon NIH-sponsored research, and (b) publishers of professional journals that have accepted those articles for publication and to whom copyright interests have been conveyed. These copyright interests are well-established under federal law and NIH has no authority to alter them on its own. Consequently, NIH must, as a general matter, obtain permission from those authors who have retained a copyright interest *and* the publishers in order to distribute and/or display accepted manuscripts of the articles to the general public.

- The plan is fatally flawed as it fails to recognize the need to obtain copyright permission from authors and/or publishers to distribute or display manuscript copies to the public. Suggestions that such permission may be excused by resort to the "fair use" defense or NIH's "federal purpose" license in the manuscripts are without merit. In addition, as to grantees under the Small Business Innovation Research program, NIH has no authority even to seek such permission without approval of the U.S. Small Business Administration.

- The plan threatens to undercut the Bayh-Dole Act by interfering with technology transfer. NIH has recognized in Congressional testimony that scientific publications are an important component of technology transfer for NIH-sponsored research, and weakening that technology transfer component would represent poor public policy. NIH's plan also undermines the principle of the Bayh-Dole Act that the private sector is the preferable vehicle to move federally-funded research results to the public and the marketplace.

- Because NIH is subject to the Freedom of Information Act and intends to place the accepted manuscripts into an NIH database, manuscripts submitted to NIH likely constitute "printed publications" under U.S. patent laws. Consequently, the date such a draft manuscript is submitted to NIH would trigger the running of the one-year time period for filing a U.S. patent application covering research disclosed in the manuscript, and patent applications filed after that date in foreign countries that do not provide a grace period similar to U.S. law will be time-barred. This is a change from current

[2] The Notification, which refers to NIH's "public access" proposal both as a "plan" and a "policy," is silent as to whether the final plan/policy will be implemented through rule-making. As discussed *infra*, notice and comment rulemaking under 5 U.S.C. § 553 by the Department of Health and Human Services ("DHHS") is required for NIH's plan/policy. Reference herein to NIH's plan/policy as such does not waive the position that a DHHS rule is required here.

practice, which relies on the date of journal publication, and risks significant adverse consequences for researchers and NIH.

- The NIH plan constitutes a legislative rule-making under the Administrative Procedure Act. However, NIH lacks the authority to adopt this plan because it is without legislative rule-making power, and in any event cannot adopt a plan that is at variance with a controlling DHHS regulation. Even if NIH could undertake legislative rule-making, formal notice and a public comment opportunity are required. The current notice is legally inadequate for legislative rule-making because it fails to provide sufficient details of the plan or the data upon which NIH has relied to afford the public a meaningful comment opportunity.

- Because the Regulatory Flexibility Act applies to NIH's plan, NIH cannot proceed unless it undertakes the regulatory flexibility analyses required under the Act. Moreover, the Associations, as small entities under the Act, would be entitled to judicial review of NIH's compliance (or non-compliance) with the Act.

- The Paperwork Reduction Act applies to NIH's plan. NIH is required by law to comply with that Act, and failing to do so, NIH cannot enforce any penalty on NIH grantees who decline to submit manuscripts as required by NIH's plan.

- OMB Circular A-76 applies to NIH's plan. NIH cannot implement its plan unless the agency performs a cost-comparison study and determines that its plan to have NIH distribute NIH-sponsored research results using accepted manuscripts is less expensive for the federal government than the present system of scientific publishing.

- Because NIH's plan would interfere with constitutionally protected rights, NIH would need to satisfy analytical and reporting requirements to OMB as to potential obligations imposed by the Just Compensation Clause of the Fifth Amendment. Additionally, while DHHS could, conceivably, change its grant regulation on grantee copyright ownership to authorize NIH's plan, such a change would require OMB approval for a deviation from OMB's uniform grant rules.

II. THE ASSOCIATIONS

A. THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

AAI, a not-for-profit professional association founded in 1914, is the leading association of immunologists in the world. AAI has more than 6,500 regular and trainee members. AAI's membership consists mainly of researchers, scientists and physicians, many of whom are NIH-grant recipients who publish articles reporting on their NIH-sponsored research.[3] These individuals would be directly affected by NIH's plan.

[3] To be admitted as a regular member of the AAI, an applicant must meet one of the following criteria: (1) possess a Ph.D. (or equivalent graduate degree, *e.g.* D.Sc.) in immunology or related disciplines, or an M.D. (or equivalent medical degree, *e.g.*, D.D.S.) and be the first

AAI publishes *The Journal of Immunology* ("*The JI*"), one of the leading professional, peer-reviewed journals dedicated to immunology. A subscription to *The JI* is provided to AAI members in a print version and on-line as part of membership dues. In addition, non-member subscriptions (personal subscriptions and institutional single and multi-site licenses) for print copies and/or electronic access can be purchased. *The JI* has over 8,000 subscriptions. Because online subscribers include institutions that make the publication available to a wide readership, the number of readers of *The JI* cannot be accurately estimated. However, *The JI* online has over 1 million views per year. In 2003, 53 percent of the articles published in *The JI* acknowledged NIH funding.

Upon submission of manuscripts, authors convey their copyright rights in their articles to AAI in consideration for AAI's peer-review process and publication of the article.[4] Expenses incurred in the publishing of *The JI* are off-set by revenue from subscriptions, publication fees, and advertising.

In 2004, the NIH Library purchased a single site license (one print copy included as well) for *The JI* that extends to in excess of 12,000 full-time equivalent NIH employees. This NIH subscription for *The JI* had 15,065 total accesses (entries into the site) between January 2004 and June 30, 2004. A second subscription for one print copy only was purchased by the NIH National Library of Medicine "Index Medicus." There also are many individual AAI member subscriptions for print and online and several non-member subscriptions for print only registered to persons at the NIH Bethesda campus and a variety of subscriptions for NIH Institutes located in cities other than Bethesda, MD.

B. THE AMERICAN PHYSIOLOGICAL SOCIETY

APS is a not-for-profit professional association devoted to fostering education, scientific research, and dissemination of information in the physiological sciences. APS was founded in 1887 with 27 members and now has nearly 11,000 members who are involved in physiological research and education. A significant number of APS members are NIH-grant recipients who publish articles based upon NIH-sponsored research and who would be directly affected by NIH's plan.

APS publishes 14 peer-reviewed professional journals in the field of physiology as detailed in the APS policy comments. Authors publishing in these journals convey the copyright rights in their articles to APS in consideration for APS's peer-review process and publication of

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author of one significant original publication on an immunological topic in a reputable, English language refereed journal;* or (2) be an established scientist with substantial achievement in a related discipline and have at least one collaborative paper on an immunological topic in a reputable, English language refereed journal.

*These requirements may be waived under exceptional circumstances if a candidate shows evidence of other appropriate training and/or substantial research accomplishment.

[4] AAI releases its copyright back to the authors if the paper is not published.

the article. In 2003, 50% of the articles published by the APS journals acknowledged NIH funding.

III. THE NOTIFICATION, NIH'S PLAN AND THE ASSOCIATIONS' STANDING TO COMMENT

A. BACKGROUND EVENTS IN CONGRESS PRIOR TO THE NOTIFICATION

In 2003, the House Appropriations Committee requested a report from NLM by March 1, 2004 on the subject of access to taxpayer-funded research. H. R. Rep. No. 108-188, at 89 (2003), accompanying the House of Representatives Fiscal Year 2004 Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations bill.[5] In response, NIH submitted, on behalf of NLM, a paper to the Committee titled "Access to Biomedical Research Information," dated May 2004 ("May 2004 NIH Report"), discussed *infra*.

In July 2004, the House Appropriations Committee noted that it had become "aware of" and supported a proposal to make the complete text of articles and supplemental material generated by NIH-funded research available on PMC, the digital library of the NLM. H. R. Rep. No. 108-636, at 108 (2004), accompanying the Fiscal Year 2005 Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations bill ("FY 2005 Labor/HHS Appropriations bill"). The Committee recommended that:

> NIH develop a policy, to apply to FY 2005 forward, requiring that a complete electronic copy of any manuscript reporting work supported by NIH grants or contracts be provided to PMC upon acceptance of the manuscript for publication in any scientific journal listed in the NLM's PubMed directory. Under this proposal, NLM would commence making these reports, together with supplemental materials, freely and continuously available at six months after the publication, or immediately in cases in which some or all of the publication costs are paid with NIH grant funds. . . .

Id. The Committee Report also contains a specific direction that NIH render a report on implementation of this "proposal":

> NIH is instructed to report to the Committee by December 1, 2004 about how it intends to implement this policy, including how it will ensure the reservation of rights by the NIH grantee, if required, to

[5] A remark in the Committee Report about "tax-payer funded research remain[ing]" in the public domain, *id.* at 89, confused NIH-sponsored research with the researcher's publication concerning that research. The publication is the work of the researcher/author and, as explained *infra*, the work is the author's copyrightable property in which the federal government has a limited license for federal purpose uses. As discussed *infra* (section IV.A.6), the NIH plan goes well beyond the permissible limits of NIH's federal purpose license.

> permit placement of the article in PMC and allow appropriate public uses of this literature.

Id. NIH posted its proposal on its own website on September 3, 2004, http://www.grants2.nih.gov/grants/guide/notice-files/NOT-OD-04-064.html. The FY 2005 Labor/HHS Appropriations bill was adopted by the House on September 9, 2004.[6] The Notification in the Federal Register followed eight days later on September 17, 2004.[7]

B. NIH'S NOTIFICATION OF ITS PLAN

The NIH plan is proffered, ostensibly, "to facilitate enhanced public access to NIH health-related research information." 69 Fed. Reg. 56074 (all further quotation of plan language is to this cited reference). NIH's Notification, however, *does not* facilitate public comment as it omits significant information concerning the implementation and impact of the plan. For instance, while the plan would certainly affect existing intellectual property rights of NIH grantees and researchers, harm small businesses, substantially change NIH grant policy, contravene existing DHHS regulation and reduce funding available for NIH's research, none of these consequences are mentioned in the Notification.[8] While no doubt hastily prepared in view

[6] As of this submission, the FY 2005 Labor/HHS Appropriations bill has not been adopted by the Senate nor approved by the full Congress.

[7] As discussed *infra*, such Congressional directives not found in a statute do not have the force and effect of actual legislation passed by both houses of Congress and signed by the President. That the NIH plan is driven in some haste by a Congressional reporting deadline is largely confirmed by NIH's website description of the final policy process: "Once the final policy is published, NIH will report to Congress on its implementation." NIH Public Access -- Background Information, at 2 (dated Oct. 13, 2004); http://www.nih.gov/about/publicaccess/publicaccess_background.htm. If the report referenced in the foregoing quote is meant to refer to the House Appropriations Committee December 1 deadline, then NIH will have but two weeks from submission of these comments (and no doubt others) within which to formulate its final "policy", hardly an amount of time sufficient to consider and address the substantive concerns raised herein.

[8] The origin and details of NIH's plan are shrouded in mystery. In the May 2004 NIH Report to the House Appropriations Committee (concerning public access to NIH-sponsored research), NIH made no mention of such a plan. According to the Notification, NIH has held a series of meetings with "interested parties" concerning "public access" ideas, but the Notification does not indicate that the plan was vetted in those meetings, nor does it reveal whether NIH used information shared in those meetings to develop the plan. Indeed, key aspects of the plan as set forth in the Notification are at odds with our understanding of comments made by NIH officials at those meetings. NIH clearly made the House Appropriations Committee "aware of" key details of the plan in July 2004, *see* H. R. Rep. No. 108-636, at 108, but waited until as late as September to inform the public of the plan via the Federal Register, and even then only provided the sketchy information contained in the Notification.

of the pending December 1 deadline, the fact remains that the public cannot meaningfully comment on plan details known only to NIH.[9]

So far as can be gleaned from the limited information in the Notification, the plan appears to consist of three elements – manuscript submission, archiving, and dissemination to the general public without charge. First, concerning manuscript submission, NIH intends "to request that its grantees and supported Principal Investigators provide NIH with electronic copies of all final version manuscripts upon acceptance for publication if the research was supported in whole or in part by NIH funding." "Final version manuscript" is described by NIH as "the author's version resulting after all modifications due to the peer-review process." While NIH terms this version as "final," it is a well known fact that such a version of a manuscript is *not* final; rather, it is a peer-reviewed version of the article that will be further edited, often significantly, by the professional journal prior to publication in the journal.[10]

Also, while NIH denominates submission of the draft manuscript as a "request," manuscript submission is effectively mandatory.[11] The Notification states that a grantee's electronic manuscript submission will "be monitored" by NIH as part of the annual grant review and close-out process. The obvious implication is that a grantee must comply with the "request" or risk an adverse review of the grantee's performance. Indeed, as the Notification states, draft manuscript submission pursuant to the plan "will fulfill the *requirement* of the provision of one copy of each publication in the annual or final progress reports." (Emphasis added.)[12] As NIH well knows, an adverse annual grant review can result in the withholding of NIH grant funding for subsequent years, and an adverse close-out can provide NIH grounds for denial of subsequent grants to the grantee.

Finally, the submission requirement is far-reaching, encompassing all research grants, cooperative agreements, and contracts, as well as National Research Service Award fellowships, and would apply to grantees and PIs performing research supported "in whole or part" by NIH

[9] NIH's own description of its plan recognizes that the Notification does not contain a "clear description" of the agency's intentions. In discussing the "final policy" in the NIH Public Access – Background Information, NIH states: "The final policy will take into account the input that NIH receives on the issue, and will outline a clear description of the agency's position and planned actions in the area of public access." NIH Public Access – Background Information, at 2 (Oct. 13, 2004). This remark alone admits that the Notification does not provide a clear description of either the agency's position or planned actions.

[10] NIH acknowledges this point later in the Notification when it states that, upon request, the author's "final version of the publication will be replaced in the PMC archive by the final publisher's copy . . . ."

[11] This view is consistent with the House Committee Report underlying the FY 2005 Labor/HHS Appropriations bill, which directs NIH to develop a policy "requiring" manuscript submission. H.R. Rep. No. 108-636, at 108.

[12] In this respect, the Notification blithely ignores that the plan would require submission of a pre-publication manuscript with the annual or final progress report, in contrast to the current requirement for submission of a manuscript that has been published in final form by the journal.

funds. This would cover manuscripts submitted to review journals, as well as primary research journals, and would be triggered by research for which NIH-funding was but a small part.

The second element of the plan is that NIH will "archive these manuscripts and any appropriate supplementary information in PubMed Central (PMC)."[13] NIH states that PMC archiving of these draft materials is desirable because NIH "considers" these pre-publication "final" manuscripts to be "an important record of the research funded by the Government." Heretofore, however, NIH has not considered a pre-publication manuscript version to be of import, as the NIH awarding offices receive the *published, for the record* copy of every article that results from an NIH grant-supported project. NIH Grants Policy Statement ("NIHGPS"), Part I, at 113 ("One copy of each publication resulting from work performed under an NIH grant-supported project must accompany the annual or final progress report submitted to the NIH awarding office.") Again, the reasoning here is known only to NIH because the Notification does not explain how NIH reached the counter-intuitive determination that the pre-publication draft is "an important record of the research" when NIH is entitled under the NIHGPS to receive the published version of the article.[14]

The Notification also does not address the terms and conditions under which authors must deposit their manuscripts in PMC. The current PMC depository agreement for journals to deposit individual articles, titled "Agreement to Deposit Individual Open Access Articles in NIH PubMed Central Archive" ("PMC Deposit Agreement") (Attachment 1 hereto), requires depositors to embrace the so-called "Open Access" principles, essentially giving public access without charge to all deposited materials, concomitantly devaluing the copyright holder's interest in the materials. Cognizant of the potential exposure stemming from such devaluation, the PMC Deposit Agreement also requires that the depositor indemnify and hold harmless PMC for any copyright infringement. Should the PMC Agreement be employed in concert with the NIH plan, authors who have assigned or otherwise conveyed exclusive copyright rights in their manuscripts to professional journals would not be able to deposit their manuscripts with PMC, because the PMC Deposit Agreement contravenes the copyright assignment/transfer to the journals.[15]

The third element of NIH's plan is that PMC will release the pre-publication manuscripts to the public, without charge, *at some point within* six months after journal publication: "Six months after an NIH-supported research study's publication -- or sooner if the publisher agrees -- the manuscript will be made available freely to the public through PMC." Although the

[13] PMC is "NIH's digital repository for biomedical research," under the auspices of NLM.

[14] The only conceivable "record" use of a draft manuscript would be to ascertain the editing changes between the draft manuscript and the final published version. NIH is obviously not interested in that use, however, because the Notification indicates NIH will accept the draft in lieu of the final version and thus will not have the final version with which to make a comparison.

[15] Further recognizing the inadequacies of the Notification, NIH provides a series of questions and answers on the NIH website concerning the "NIH public access policy" ("NIH Q and A"), http://www.nih.gov/about/publicaccess/publicaccess_QandA.htm. The terms and conditions of the plan's deposit/archive agreement are conspicuously *not* discussed therein.

notification states that the trigger point will be "publication," the point of publication is not defined. For journals that already publish accepted manuscripts immediately, the six month period would commence several months before the journal issue is published. For those journals, the six month period may be no more than three months, and in some cases, possibly fewer.[16]

As apparent justification, NIH states that its plan is intended to permit availability of scientific information arising from NIH-sponsored research to "scientists, heath care providers, students, teachers, and the many millions of Americans searching the Web to obtain credible health-related information" and that "establishing" a "comprehensive, searchable electronic resource of NIH-funded research results" and providing "free access to all" is "perhaps" the "most fundamental way to collect and disseminate this information."

Unstated by NIH is that PMC would distribute and/or display these manuscripts via the Internet, to the public, at the same time (or before) the professional journals provide the finished articles to the public on a subscription basis, thereby directly competing with the journal publishers. NIH apparently does recognize, however, that this will have adverse economic consequences for the not-for-profit biomedical publication sector, because NIH also states that "free access" to research results must be "balance[d]" against the "ability of journals and publishers to preserve their critical role in the peer-review, editing, and scientific quality control process[,]" and that NIH must consider the "economic and business implications of any changes to the current paradigm . . . ."[17]

The Notification also fails to provide information as to whether the plan would be applied prospectively or retrospectively and does not address whether or how existing NIH regulations or policies will be affected or amended by the plan. Without the agency's views on these critical issues, meaningful public comment is frustrated.

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[16] Publication may thus occur as early as the date when an author electronically transfers the manuscript to PMC, but in any event no later than the date when one of the Associations' journals posts the manuscript on the journal's website as an "article in press." Depending on publication date, the six months could expire before publication and not later than two to three months after publication, clearly well short of six months.

[17] NIH appears to have reached a conclusion on all of this even before the public comment period has closed. NIH's Q and A, posted October 13, 2004, states that the plan will not have a "substantial impact" on scientific publishing. NIH Q and A, at question 12. As discussed in the Associations' separate comments and herein, that assertion is simply wrong, and it is notable that NIH's statement has no cited support. How NIH could reach this conclusion before the comment period closes is known only to NIH.

C. THE ASSOCIATIONS' STANDING TO COMMENT

The Associations have standing in their own right, as not-for-profit publishers of professional biomedical journals, to comment upon and object to NIH's plan. First, the plan would result in PMC, an entirely taxpayer-funded entity, becoming a manuscript distributor in direct competition with the Associations' journals. Second, as publishers, the Associations obtain copyright ownership or assignments from authors that give them the exclusive right to publish the respective articles (and the Associations actively defend these copyright interests against infringement). These copyright interests, critical to the Associations' ability to maintain the integrity of the scientific content of their journals and recover the costs associated with peer review and publication, would be substantially reduced in value by NIH's plan.

The Associations also have standing on behalf of their members, many of whom are NIH grant recipients, PIs and/or authors who would be directly affected by the plan. First, as NIH-grant recipients and PIs, they are the direct target of NIH's manuscript submission "request." Second, as authors, they have copyright interests that will be adversely affected by the plan. As authors, members typically assign their copyright interest to a professional journal as part of the peer-review and publication process. Because the plan diminishes the value of authors' copyright interests in their works, authors will likely shoulder higher direct publication costs. Third, should NLM employ the PMC Deposit Agreement, member-authors will face the unenviable choice of, on the one hand, not depositing the manuscripts with PMC to avoid vitiating their copyright assignment, and thereby risk adverse NIH annual reviews, or, on the other hand, depositing with PMC and standing behind the indemnification/hold harmless provision of the PMC Deposit Agreement. In sum, substantial economic and legal interests of the Associations would be affected by the plan.

IV. THE ASSOCIATIONS' LEGAL POSITION IN OPPOSITION TO NIH'S PLAN

The Associations are deeply concerned that NIH's plan would infringe on the intellectual property rights, principally copyright, held by NIH-sponsored biomedical researchers and the professional, peer-reviewed journals that publish their research. These intellectual property rights, long-established and specifically recognized by federal law, have served as the principal economic pillar of biomedical journals sponsored by not-for-profit professional societies such as the Associations. The researchers and the publishers rely on the researcher's assignment of copyright in the researcher's work as the basis of the highly effective peer-review publication system, funded in significant part by subscriptions to the journals. NIH's plan would diminish the value of the copyright, as the NLM would become a "free" distributor and/or displayer of the journals' "copyrighted" manuscripts in direct competition with the journals' final published issue.

Were NIH's plan to be adopted, it almost certainly would result in financial injury to, and possibly the demise of, many long-established biomedical, peer-reviewed journals sponsored by not-for-profit professional societies, including those published by the Associations. In short, few not-for-profit societies could long afford to publish journals in competition with a U.S. government entity that distributes the societies' own publications for free over the Internet. Without these journals, the public would lose the primary publication channel through which biomedical research information is now disseminated.

At a minimum, NIH-funded researchers and their sponsoring institutions would face substantial increased costs for publication of both NIH and non-NIH-funded research as they absorb publication costs now borne by journal subscribers. These higher costs would likely be passed on to NIH and other grantors, which in turn would reduce NIH funding available for biomedical research. The result would be a restructuring of the existing and highly effective system of peer-reviewed biomedical research publication by not-for-profit professional societies. NIH's Notification gives no indication that NIH has considered the implications of such developments. The plan also fails to address the impact on small business, as it adversely impacts small business intellectual property rights under the Small Business Innovation Development Act.

The plan also fails to consider its implications on technology transfer of inventions patented by universities and other non-profits under the Bayh-Dole Act, or that the plan undermines the principle of the Bayh-Dole Act that the private sector is the preferred method to disseminate NIH-sponsored research results to the public. The plan also has significant implications, also unaddressed, on the timing of patent applications.

The Associations further submit that NIH does not have the regulatory authority to adopt such a plan. Moreover, even if NIH had authority to so act, which it does not, NIH would have to proceed by rulemaking, with sufficient notice and comment, and comply with the Regulatory Flexibility and Paperwork Reduction Acts and with OMB Circular A-76, none of which NIH is doing at this time. Under these circumstances, NIH should abandon the plan.

A. NIH'S PLAN TO DISTRIBUTE MANUSCRIPTS TO THE PUBLIC WOULD INFRINGE UPON INTELLECTUAL PROPERTY RIGHTS OF NIH GRANTEES AND SPONSORED RESEARCHERS, AND SCIENTIFIC JOURNALS.

1. Federal Law Authorizes Grantees And Contractors To Copyright Works Related To Federal Grants And Contracts.

An understanding of the copyright ownership interest of federal grantees in their work is essential to an appreciation of the copyright interests put at stake by the NIH plan. As authorized by Article I, Section 8 of the U. S. Constitution (empowering Congress to establish and regulate patents and copyrights), Congress enacted the Copyright Act of 1976, Pub. L. No. 94-553, 90 Stat. 2541 (1976) (codified, as amended, at 17 U.S.C. §§ 101 *et seq.* ("1976 Act")).[18] Under the 1976 Act, copyright protection subsists in "original works of authorship fixed in any tangible medium of expression, now known or later developed," 17 U.S.C. § 102(a), and copyright ownership "vests initially in the author or authors of the work," 17 U.S.C. § 201(a).

[18] The 1976 Act was the first major revision of U.S. copyright laws since the Copyright Act of 1909, 35 Stat. 1077 (1909).

The 1976 Act does not preclude federal contractors and grantees who are "authors" [19] from copyrighting their "original works" because the work has been financially supported by the federal government. *Schnapper v. Foley*, 667 F.2d 102, 109 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 948 (1982) (neither the 1909 Act nor the 1976 Act proscribed registration of federally-commissioned works, and such rights may be assigned by the contractor/grantee); *Hart v. Sampley*, 1992 WL 336496 (D.D.C. 1992) (copyright claim permitted in Vietnam Veterans Memorial; government work restriction only applies to works of government employees). *See also Rubin v. Boston Magazine Co.*, 645 F.2d 80 (1st Cir. 1981) (grantee may claim copyright in work supported by Institute of Mental Health grant). Thus, it is now well-established that federal contractors and grantees may copyright their created works even though those works may arise from government-funded projects. [20] M. Nimmer & D. Nimmer, *Nimmer on Copyright*, § 5.13[B][2], at 5-98 through 5-101 (2004); Patry, *Copyright Law and Practice* 350-53 (1994). *See also* Tresansky, *Impact of Copyright Act of 1976 on the Government*, 35 Fed. B.J. 21 (1978) (while government employees have generally been prohibited from copyrighting works prepared on government time, federal contractors and grantees are permitted to copyright their works largely without limitation); Price, *Copyright in Government Publications: Historical Background, Judicial Interpretation and Legislative Clarification*, 74 Mil. L. Rev. 19, 52 (1976) (reaching same conclusion as to the then pending 1976 Act, but questioning legal basis under the 1909 Act).

2. Controlling Federal Rules And Regulations Expressly Permit Copyright Of Any Work Developed Under Grant Awards.

Office of Management and Budget ("OMB") Circular A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Not-for-Profit Organizations (Nov. 19, 1993, revised Sept. 30, 1999) ("Circular A-110") governs the administration of federal grants and essentially requires uniform grant administration by all federal agencies. Circular A-110 expressly permits grant recipients to copyright any copyrightable work developed under the grant award, subject only to a reservation of a "federal purpose" license by the awarding agency:

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[19] While "author" is not defined in the 1976 Act, it has long been construed to mean "he to whom anything owes its origin." *Burrow-Giles Lithographic Co. v. Sarony*, 111 U.S. 53, 54 (1884).

[20] This conclusion is drawn, in part, from legislative history of the 1976 Act indicating that Congress specifically considered the issue of copyrighting works arising from federally-funded programs and deliberately chose not to include federal contractors/grantees under the government works prohibition (covering government employees) or to otherwise prohibit copyrighting of federally-sponsored work. H.R. Rep. No. 1476, 94th Cong., 2d Sess., at 59 (1976) ("The bill deliberately avoids making any sort of outright, unqualified prohibition against copyright in works prepared under Government contract or grant."). Rather, Congress expected that copyrighting of works arising from federally-sponsored projects would be addressed by the Executive Branch. *Id.*

> [__].36 Intangible property.
>
> (a) *The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award.* The Federal awarding agency(ies) reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

Circular A-110, at 25-26 (emphasis added). This provision has remained unchanged since 1993 when the current version of Circular A-110 was issued. OMB Final Revision to OMB Circular A-110, 58 Fed. Reg. 62992, 63001 (Nov. 29, 1993).[21] Circular A-110 is applicable to all Federal agencies, and its provisions supersede all inconsistent terms in agency nonregulatory materials such as program manuals and handbooks, absent an approved OMB deviation. *Id.* at 62993 (§ 3), 63995 ([__].3 and [__].4). Indeed, Federal agencies are directed to "adopt the language of the Circular" unless different provisions are required by statute or are approved by OMB. *Id*. at 62993 (§ 5).

As required by Circular A-110, DHHS has adopted verbatim OMB's directive in Circular A-110 as to the copyright of works by grantees:

> (a) *The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award.* The HHS awarding agency reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

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[21] The language in the first Circular A-110 promulgated in 1976 was only slightly different:

> Except as otherwise provided in the terms and conditions of the agreement, the author or the recipient organization is free to copyright any books, publications, or other copyrightable materials developed in the course of or under a Federal agreement, but the Federal sponsoring agency shall reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use, the work for Government purposes.

Circular A-110, Attachment N, § 8.b. (1976), 41 Fed. Reg. 32016, 32030 (July 30, 1976). The history of Circular A-110 does not indicate a substantive change was intended by the substitution of "Federal" for "Government" in the 1993 version. OMB, Proposed Revision of Circular A-110, 57 Fed. Reg. 39018 (Aug. 27, 1992).

45 C.F.R. § 74.36 (emphasis added).[22] Section 74.36 is part of DHHS's general regulation on DHHS grants, 45 C.F.R. Part 74, Administration of Grants, and DHHS acknowledged when adopting 45 C.F.R. Part 74 that it was bound to follow Circular A-110 (absent an exception from OMB). DHHS, Interim Final Rule; Request for Comments, 59 Fed. Reg. 43754 (Aug. 25, 1994).[23] *See also id.* at 43762 (§ 74.3; the regulation supercedes all inconsistent program manuals, handbooks, and other nonregulatory materials).

3. NIH Policy Expressly Grants NIH Recipients Ownership In Data Rights And Authority To Copyright.

Consistent with DHHS controlling regulations, the NIHGPS acknowledges that grantees own the data that results from grant-supported projects, and may copyright publications, data or other copyrightable work developed under NIH grants without NIH permission, subject to NIH's reservation of a royalty-free, nonexclusive and irrevocable license for the federal government to reproduce, publish or otherwise use the material or authorize others to do so for federal purposes:

> Rights in Data (Publication and Copyrighting)
>
> *In general, grantees own the rights in data resulting from a grant-supported project.* Special terms and conditions of the award may indicate alternative rights, e.g., under a cooperative agreement or based on specific programmatic considerations as stated in the applicable RFA. *Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval*. Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. *In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to*

[22] The provision is similar to that first adopted by DHHS's predecessor in 1978. *See* 43 Fed. Reg. 34075, 34097 (Aug. 2, 1978).

[23] DHHS has made 45 C.F.R. Part 74, Administration of Grants, specifically applicable to NIH. Additionally, DHHS's regulation governing NIH grants, 42 C.F.R. Part 52a, National Institutes of Health Center Grants, specifically incorporates 45 C.F.R. Part 74 by reference. 42 C.F.R. § 52a.8. Similar provisions are found in other DHHS regulations governing other NIH grants, *e.g.*, 42 C.F.R. Part 52b.8. As noted above, Part 74 includes Section 74.36 covering copyrights. Further, DHHS's general regulations on research grants, 42 C.F.R. Part 52, Grants for Research Projects, are specifically applicable to the PHS and its components, such as NIH. 42 C.F.R. § 52.1(a). DHHS has made its general grants administration regulation, 45 C.F.R. Part 74, Administration of Grants, specifically applicable to research grants. 42 C.F.R. § 52.8. Part 74 includes DHHS's copyright provision concerning grants, 45 C.F.R. § 74.36; thus, section 74.36 is expressly applicable to NIH research grants.

> *authorize others to do so for Federal purposes.* Data developed by a consortium participant also is subject to this policy.

NIHGPS, Part I, at 113 (emphasis added).

Additionally, the NIHGPS encourages grantees to assert their copyright to promote the sharing of research data and knowledge:

> As a means of sharing knowledge, *NIH encourages grantees to arrange for publication of NIH-supported original research in primary scientific journals. Grantees also should assert copyright in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.* Journal or other copyright practices are acceptable unless the copyright policy prevents the grantee from making copies for its own use (as provided in 45 CFR 74.36 and 92.34). The disposition of royalties and other income earned from a copyrighted work is addressed in "Administrative Requirements—Management Systems and Procedures—Program Income."
>
> . . .
>
> One copy of each publication resulting from work performed under an NIH grant-supported project must accompany the annual or final progress report submitted to the NIH awarding office (see "Administrative Requirements—Monitoring—Reporting—Non-Competing Grant Progress Reports" and "Administrative Requirements—Closeout—Final Reports—Final Progress Report").

Id. (italicized emphasis added).[24]

4. NIH's Plan Likely Infringes On Copyright Ownership Interests And Leaves A Myriad Of Issues Unresolved.

Given the above, it is beyond dispute that NIH grantees and sponsored researchers own the copyright to works arising from NIH-sponsored research, subject only to the reservation of NIH's federal purpose license.[25] Included within the bundle of rights enjoyed by the copyright

[24] To the extent NIH policy may be inconsistent with Circular A-110 or with DHHS's adoption thereof, the NIH policy would be superseded.

[25] According to federal copyright law, the duration of the researchers/authors' copyright would be at least the author's life plus 70 years (single author), life plus 70 years of the last surviving author (joint), or the earliest of 95 years from first publication or 120 years from creation (work for hire). 17 U.S.C. § 302.

holder is the exclusive right to reproduce the copyrighted work, to distribute copies of the copyrighted work to the public and to publicly display the work. 17 U.S.C. § 106(a). Indeed, the 1976 Act gives "copyright owners control over most, if not all, activities of conceivable commercial value." *Playboy Enterprises, Inc. v. Frena*, 839 F. Supp. 1552, 1555 (M.D. Fla. 1994) ("Engaging in or authorizing any of these [statutory] categories without the copyright owner's permission violates the exclusive rights of the copyright owner and constitutes infringement of the copyright. *See* 17 U.S.C. § 501(a).")[26] *Accord, Feist Publications, Inc. v. Rural Telephone Service Co.*, 499 U.S. 340, 361-63 (1991).

Moreover, NIH encourages grantees to arrange for publication of NIH-sponsored research *and* "to assert copyright in scientific and technical articles" in order "to effect publication." As NIH urges (and obviously supports), NIH-sponsored authors *do* assert their copyright in their manuscripts "to effect publication." To that end, they assign or transfer the copyright to the professional journals that undertake the peer-review process, editing, and publishing of the manuscripts. The Associations and their authors follow this very practice.

It is precisely this construct that is threatened by NIH's plan. Under the plan, NIH-sponsored researchers will be "requested" to deposit with PMC their "final manuscripts" after peer-review has been undertaken by a journal, and PMC intends to distribute and/or display the final manuscript to the public no later than six months after journal publication.[27] To effect publication (as urged by NIH), most authors traditionally have assigned their copyright interests

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[26] Concerning "display," the court in *Frena* specifically noted:

> The concept of display is broad. *See* 17 U.S.C. § 101. It covers "the projection of an image on a screen or other surface by any method, the transmission of an image by electronic or other means, and the showing of an image on a cathode ray tube, or similar viewing apparatus connected with any sort of information storage and retrieval system." H.R.Rep. No. 1476, 94th Cong., 2d Sess. 64 (Sept. 3, 1976), reprinted in 1976 U.S.Code Cong. & Admin. News 5659, 5677. The display right precludes unauthorized transmission of the display from one place to another, for example, by a computer system. See H.R.Rep. No. 1476, 94th Cong., 2d Sess. 80 (Sept. 3, 1976), reprinted in 1976 U.S.Code Cong. & Admin. News 5659, 5694; JAY DRATLER, JR., Intellectual Property Law: Commercial, Creative and Industrial Property § 6.01[4], at 6-24 (1991).
>
> "Display" covers any showing of a "copy" of the work, "either directly or by means of a film, slide, television image or any other device or process." 17 U.S.C. § 101. However, in order for there to be copyright infringement, the display must be public. A "public display" is a display "at a place open to the public or ... where a substantial number of persons outside of a normal circle of family and its social acquaintances is gathered." 2 MELVILLE B. NIMMER, Nimmer on Copyright § 8.14[C], at 8-169 (1993).

839 F. Supp. at 1557.

[27] As discussed *supra*, the "request" is not voluntary and the actual period between journal publication and PMC distribution is likely to be considerably shorter than six months.

to the publisher. Thus, for PMC to distribute and/or display these copyrighted materials to the public, PMC will require permission of the copyright holder. Absent consent from authors and journals, PMC's distribution to the public would constitute copyright infringement. [28,29] *See College Entrance Examination Board v. Pataki*, 889 F. Supp. 554 (N.D.N.Y. 1995) (state requirement to make college entrance examinations available to the public constitutes infringement unless excused by "fair use" doctrine).

College Entrance Examination Board presented facts virtually on-point with NIH's plan. In that case, the State of New York mandated that secure college entrance examination test forms be "distributed" to the New York education commissioner to enable the commissioner to distribute the examinations to the public. The court found the scheme to constitute a *prima facie* case of copyright infringement:

> Given the case law addressing the copyrightability of materials such as those at issue here, there can be no dispute that the SAT I, GRE, and TOEFL forms and questions are protected by the Copyright Act. *See* 17 U.S.C. § 102(a) (West 1995 Supp.); *see, e.g., AAMC II*, 928 F.2d at 521; *Educational Testing Serv. v. Katzman*, 793 F.2d 533, 538-39 (3rd 1986). In addition, it is uncontroverted that the moving plaintiffs regularly register their test forms with the United States Copyright Office. *See* Plaintiffs' Memorandum of Law at 5 and n. 7. Finally, there can be no dispute that the STA requires the moving plaintiffs to distribute to the commissioner, and through him the general public, copies of

[28] The federal government can be liable to the copyright owner for copyright infringement as Congress expressly has provided that the copyright laws can be "infringed by the United States." 28 U.S.C. § 1298(b). If PMC were to disseminate manuscripts as envisioned by NIH's plan without obtaining permission from the authors and/or their publishing journals, depending upon which is the "copyright owner," claims will lie (exclusively) against the United States for copyright infringement. *Id.* While the full extent of such damages cannot be determined presently, considering that NIH-sponsored authors are estimated to prepare 10 percent of the articles published annually in professional biomedical publications, infringement damages could be considerable.

[29] This aspect of the NIH plan implicates Executive Order No. 12630, 53 Fed. Reg. 8859 (Mar. 15, 1988), which addresses governmental actions that interfere with constitutionally protected property rights, and with which NIH appears not to have complied. Agencies are admonished to "be sensitive to, anticipate, and account for, the obligations imposed by the Just Compensation Clause of the Fifth Amendment in planning and carrying out governmental actions so that they do not result in the imposition of unanticipated or undue additional burdens on the public fisc," *id.* § 3(a), and, in furtherance thereof, must satisfy a number of analytical and reporting requirements, *id.* §§ 4 & 5.

> their secure test forms and the questions contained therein. Given these circumstances, the court concludes that the moving plaintiffs have established a prima facie case of copyright infringement.

889 F. Supp. at 565. NIH's plan to require that grantees and researchers "distribute" their manuscripts to PMC so that PMC may distribute or display them to the public is comparable to New York's scheme to distribute test forms to the public through the State education commissioner. The holding of *College Entrance Examination Board* applies with equal logic and force to NIH's plan.[30]

The current PMC Deposit Agreement (Attachment 1 hereto), recognizes this point as it requires, *as a condition of the deposit*, that depositing authors and copyright holders grant "all users" a "free, irrevocable, worldwide, perpetual right of access to, and license to copy, use, distribute, transmit and display the work publicly and to make and distribute derivative works . . . " PMC Deposit Agreement, at ¶ 16; *see id.* at ¶ 1 (permitting PMC participants to deposit articles only if accompanied by that license).[31]

Given the obvious importance of these copyright issues to implementation of the NIH plan, it is astonishing that the Notification is silent on copyright. The Notification seemingly envisions that NIH grantees and NIH-supported PIs will voluntarily deposit their articles with PMC in response to NIH's "request," and supposes that grantees will obtain copyright authorization from publishers and absorb the costs in their budgets. *See* Notification ("NIH trusts that the up-to-six-month delay to public archiving in PMC recommended by the policy will not result in unreasonable or disproportionate charges to grantees."). While it is hard to ascertain precisely what NIH has in mind with this oblique statement, it does appear that NIH contemplates the possibility that researchers/authors would incur costs to obtain copyright authorization from publishers (and that NIH is concerned as to the magnitude of the costs). The cost concern is certainly warranted, yet the Notification leaves the copyright and budget issues unaddressed.

Numerous other copyright and related budget issues are implicated by the plan and are also unanswered by the Notification. For instance, what are the researchers to do if publishers decline to authorize the deposit of manuscripts with PMC, or alternatively, grant consent subject

[30] That NIH would distribute and/or display the manuscripts by making them available to PMC users via Internet access and dialing into a PMC server is of little moment as that approach constitutes distribution or display under the 1976 Act. *Playboy Enterprises, Inc. v. Hardenburg*, 982 F. Supp. 503 (N.D. Ohio 1997) (posting copyrighted materials on Internet bulletin board service (BBS) constitutes copyright infringement by distribution or display); *Playboy Enterprises, Inc. v. Frena*, 839 F. Supp. 1552 (M.D. Fla. 1994) (posting copies of copyrighted materials on BBS constitutes infringement of owners right to distribute and display).

[31] The PMC Deposit Agreement is currently used for individual journal deposits. Whether NIH intends to use the PMC Deposit Agreement, or some form thereof, in connection with the plan is known only to NIH because the Notification is silent on the issue. This much is known – PMC cannot lawfully distribute manuscripts to the public without at least a copyright license, and presumably an unlimited license.

to imposition of fees that NIH considers "unreasonable" or "disproportionate"? Without the publishers' authorization, researchers cannot deposit manuscripts with PMC. (Under the current PMC Deposit Agreement, PMC will not accept them as the PMC Deposit Agreement requires an unlimited copyright license, which researchers typically cannot grant without publisher approval.) Yet, the Notification directly implies that NIH will penalize researchers and grantee institutions for failing to deposit manuscripts with PMC.

Grantees (*e.g.*, universities) will face similar conflicts with respect to employees (PIs) who author articles. NIH makes grants to grantee entities, not individual researchers. Researchers can properly decline to deposit manuscripts with PMC, placing the grantee entity at risk vis-à-vis NIH. In the instance of joint authorship, a similar conflict will arise among researchers who are NIH-sponsored and those who are not. Copyright consent of all joint authors (absent a delegation of authority to a "corresponding" author) would be required to deposit with PMC, yet, a non-sponsored researcher may properly decline to deposit.

In sum, the NIH plan effectively places researchers in the middle of a copyright shooting match. On the one hand, researchers must convey an exclusive assignment/transfer of their copyright in their "final manuscript" to a publisher in consideration for peer review and publication, which are necessary to obtain a "final manuscript" (defined in the Notification as a "final version manuscript *accepted for publication.*" (emphasis added)). On the other hand, NIH proposes requiring researchers to submit these "final manuscripts" to PMC (or risk penalties from NIH), and as a condition of depositing with PMC, researchers must convey a worldwide license to "all users" that conflicts with the copyright assignment to the publishing journal. NIH and NLM then intend to have PMC distribute and/or display articles in a manner that, absent consent, will certainly infringe on the journals' exclusive copyright assignment. Researchers would thus be caught in the middle -- liable to both the journals and NIH/NLM for violating their respective copyright assignments/transfers/license and for indemnification to NIH/NLM under the PMC Deposit Agreement (¶ 12). The plan's complete failure to address these issues renders it fatally flawed.

5. NIH's Q And A Either Misunderstands Or Ignores The Copyright Issue, and the Fair Use Defense is Not Applicable.

While the Notification is silent on copyright, NIH's Q and A does address it, but suggests NIH misunderstands the real issues:

> 14.
> Q: Can authors and journals continue to assert copyright in scientific publications resulting from NIH funding?
>
> A: Yes. The proposed policy does not affect the ability to assert copyright. Funding recipients may continue to hold copyright in works resulting from NIH-funded research, and they may assign these rights to journals in accordance with current practice. Copyright holders may enforce these copyrights as before. A member of the public viewing or downloading a copyrighted document from PubMed Central (PMC) is subject to the same

> rights and restrictions as when copying an article from the library. For example, making a copy of an article for personal use is generally considered to be a "fair use" under copyright law. For uses that fall outside of the fair use principle, permission to reproduce copyrighted materials must be obtained directly from the copyright holders. PMC currently includes a copyright notice alerting the public to the rights of the copyright holders and will continue to post this notice as it has done in the past.

For the reasons explained above, this conclusory assumption is simply wrong. If recipients "assign these rights to journals in accordance with current practice," then they cannot deposit with PMC without the journals' consent. The issue is just that simple, and NIH's failure (or refusal) to recognize this fundamental point is difficult to understand, but in any event, renders NIH's plan fundamentally deficient.

NIH's reference to "fair use" in the context of library use is also misplaced because NIH is proposing here to act, in the first instance, as a requester of documents, so that it can be, in the second instance, a document distributor, thereby placing itself in a position comparable to that of the State of New York education commissioner in *College Entrance Examination Board v. Pataki*. As a document distributor NIH falls squarely under the holding in that case where, after an exhaustive analysis using the four non-exclusive "fair use" statutory factors of 17 U.S.C. § 107, the court concluded that New York's scheme did *not* constitute fair use. 889 F.Supp. at 565-76.[32]

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[32] 17 U.S.C. § 107 provides:

> Notwithstanding the provisions of sections 106 and 106A, the fair use of a copyrighted work, including such use by reproduction of copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include--
> (1) the purpose and character of use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
> (2) the nature of the copyrighted work;
> (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
> (4) the effect of the use upon the potential market for or value of the copyrighted work.
>
> The fact that a work is unpublished shall not itself bar a finding of fair use if such finding is made upon consideration of all the above factors.

"Fair use" is an affirmative defense and the burden of proving "fair use" is on the party asserting the defense. *See, e.g., College Entrance Examination Board*, 889 F. Supp. at 564-65.

The court found that the first "fair use" factor of section 107 (the purpose and character of use, including whether such use is of a commercial nature or is for non-profit educational purposes) favored neither party as the public purposes of the State law were offset by the State's completely non-transformative use of the test documents. [33] The remaining three factors (the nature of the copyrighted work; the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and the effect of the use upon the potential market for or value of the copyrighted work) all weighed heavily in favor of the copyright holder and against the State. 889 F. Supp. at 565-76. The same outcome pertains to NIH's plan, as NIH/NLM would distribute non-transformative, complete copies of the accepted manuscripts, and the distribution would negatively impact the value of the copyrighted work, squarely on point with *College Entrance Examination Board v. Pataki.*

That NIH intends an educational or public use alone does not render the use "fair." *Marcus v. Rowley*, 695 F.2d 1171, 1174-79 (9th Cir. 1983) (distribution of multiple copies for classroom use of copyrighted materials designed for classroom use is not fair use). *See also Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 584 (1993) ("[t]he mere fact that a use is educational and not for profit does not insulate it from a finding of infringement[.]").

To the contrary, as NIH's plan involves systematic and broad distribution or display of copyrighted documents to non-governmental entities, it is outside the boundaries of "fair use" even for document reproduction, much less distribution and display. *See Williams & Wilkins Co. v. United States*, 487 F.2d 1345, 1353 & n. 12, 1354-55 (Ct. Cl. 1973) (in finding NIH/NLM's reproduction of scientific journals for *internal* NIH use to be fair use, court emphasized the "strict limitations" that kept the duplication "within appropriate confines" and suggested that "broad distribution" beyond the government would weigh against fair use), *aff'd by equally divided Court*, 420 U.S. 376 (1975). NIH's plan is more akin to the "wholesale copying and publication" found not to be fair use in *Leon v. Pacific Tel. & Tel. Co.*, 91 F.2d 484, 486 (9th Cir. 1937). *See also Williams & Wilkins Co. v. United States*, 487 F.2d 1345, 1366 (Ct. Cl. 1973) (Cowan, C.J., dissenting) and cases cited therein.

In like manner, the Department of Justice Office of Legal Counsel ("OLC"), in a memo addressing internal reproduction only (not public distribution), has stated: "Photocopying more likely will be deemed 'fair' where the photocopies are disseminated to a discrete and limited audience within the government. To the extent that copies are sold, or distributed broadly, especially outside the government, that likely would weigh against a finding of fair use." Office of Legal Counsel, Department of Justice, *Whether and Under What Circumstances Government Reproduction of Copyrighted Materials is A Noninfringing "Fair Use" under Section 107 of the Copyright Act of 1976*, at 10 (Apr. 30, 1999), *citing Williams & Wilkins*, 487 F.2d at 1353 & n. 12, 1354-55. OLC further observed: "Copying that is done 'spontaneous[ly],' for the purpose of facilitating an immediate and discrete objective, is more likely to be a fair use than systematic

[33] By "non-transformative use" the Court was referring to "simple xerographic duplication," 889 F. Supp. at 568, in which the user distributes the copyrighted work but adds nothing to the copyrighted work in the way of commentary and the like. Non-transformative use weighs *against* fair use. *Id., citing American Geophysical Union v. Texaco, Inc.*, 37 F.3d 881, 891 (2nd Cir. 1994).

'archival' copying of extensive materials for possible future use." *Id., citing American Geophysical Union v. Texaco, Inc.*, 60 F.3d 913, 919-20 (2nd Cir. 1995), *superceding* 37 F.3d 881 (2nd Cir. 1994). The Department of Justice, the government's own counsel, has rightly observed, there simply is no *per se* rule that government *reproduction* of copyrighted materials invariably qualifies as "fair use," *id.* at 2, and there certainly is no such rule as to broad, systematic distribution and/or display to the public. NIH's plan would be held to the applicable "fair use" standards, and under these standards, NIH's plan does not constitute fair use.[34]

6. NIH's Federal Purpose License Does Not Permit Distribution Of Copyrighted Material To The General Public.

NIH may consider, albeit wrongly, that these copyright issues can be avoided by resort to NIH's federal purpose license reserved under 45 C.F.R. § 74.36. As is the case with the "fair use" doctrine, discussed immediately above, the federal purpose license has never been held to permit broad, systematic dissemination of copyrighted information to the general public.[35] In fact, DHHS's reliance on the federal purpose license to authorize dissemination of copyrighted materials to the general public for commercial purposes has been expressly rejected. *Respect, Inc. v. Committee on the Status of Women*, 815 F. Supp. 1112, 1124 (N.D. Ill. 1993) (DHHS not empowered under 45 C.F.R. § 74.145 (predecessor version of section 74.36) to authorize grantee

[34] NIH's plan would not fall within the so-called library and archive "fair use safe-harbor" of 17 U.S.C. § 108. Subsection 108(g) states that the "rights of reproduction and distribution under this section [section 108] extend to the isolated and unrelated . . . distribution of a single copy . . . of the same material on separate occasions," but expressly excludes, *inter alia*, cases where the library or archive, or its employee (1) "is aware of or has substantial reason to believe that it is engaging in the related or concerted . . . distribution of multiple copies . . . of the same material," or (2) "engages in the systematic . . . distribution of . . . single or multiple copies of material described in subsection (d) [pertaining to articles or other contribution to a copyrighted collection or periodical issue]." 17 U.S.C. § 108(g)(1) & (2). (Note that this subsection does not encompass displays.) Further evidence of the limited scope of section 108 is seen in subsection (h) which permits, *inter alia*, distribution and display of copyrighted works "in a digital form" only if certain conditions are met, and then only during the *last* 20 years of any term of copyright of a published work. Similarly, subsections 108 (b) and (c), which permit certain inter-library and preservation reproduction purposes, expressly exclude documents in digital format unless they are not "otherwise distributed in that format" and not made available outside the library in that format. By contrast with section 108, NIH's plan would permit related, concerted, systematic distribution and/or display of articles *and* digital form distribution during the *first* year of the copyright term.

Whether Section 108 is a safe-harbor, as OLC contends, Office of Legal Counsel, Department of Justice, *Whether and Under What Circumstances Government Reproduction of Copyrighted Materials is A Noninfringing "Fair Use" under Section 107 of the Copyright Act of 1976*, at 15 n.12 (Apr. 30, 1999), or has altogether supplanted the *Williams & Wilkins* decision, as others have contended, *see id.*, need not be addressed here. Suffice it to state that NIH's plan is not fair use under any circumstances.

[35] Notably, neither the Notification nor the NIH Q and A mention the federal purpose license.

to print and distribute copyrighted materials funded under government grant to the general public).

The *Respect* case is highly relevant here. In that case, DHHS gave the defendant, a federal grantee, unrestricted permission to reproduce and sell copyrighted books to the public. *Id.* at 1115-1116. In a suit between Respect, the copyright holder, and the grantee, the grantee claimed that no royalties were due Respect because DHHS had authorized the defendant's distribution under 45 C.F.R. § 74.145 (an earlier version of section 74.36). *Id.* at 1122-24. The court found DHHS's authorization beyond the authority of section 74.145, as such a broad interpretation would permit the government to authorize commercial exploitation under the authority of its limited license. The court concluded, in part, that the government was "merely a nonexclusive licensee" and that such status did not allow the government to "put others into business in direct competition on a royalty-free basis." *Id.* at 1122. A contrary result, said the Court, "would turn the law of copyright on its head." *Id.*

Construing NIH's non-exclusive license for federal purposes as extending to distribution or display (or publishing) to the general public would similarly "turn the law of copyright on its head." Such a reading improperly considers "federal purpose" to mean anything the government does. But federal purpose does not mean that. *Sony Elec., Inc. v Soundview Technologies, Inc.*, 157 F. Supp. 2d 172 (D. Conn. 2001) (federal statutory mandate to incorporate V-chip into new television sets is not within a "government purpose" license reservation, rejecting argument that "government purpose" means "anything the government does.") Such a reading would convert the government's "mere non-exclusive license," *Respect*, into an unlimited license in, or ownership of, the copyright, as the term "federal purpose" would permit unlimited uses by the federal government. If federal purpose were to include dissemination to the general public, there is no purpose that would *not* be a federal purpose, thus rendering the term "federal purpose" mere surplusage.[36]

NIH's Office of Extramural Research has itself acknowledged that "federal purpose" does not include publishing data or making data available to non-governmental parties. In a 1999 filing with OMB concerning a proposed revision to Circular A-110, sec. [__].36, to extend the Freedom of Information Act to grantee research data, 64 Fed. Reg. 5684 (Feb. 4, 1999), NIH's Office of Extramural Research stated in discussing NIH's right to obtain research data from grantees for a "federal purpose":

> While NIH has the right to obtain research data from grantees "for a Federal purpose," this right typically has not been exercised. Also, it has been understood that a need for data for a Federal purpose, such as an audit, *does not mean that these data would be published or made available to others.*

[36] The *Respect* decision also finds that third party "use" of a copyrighted document ("use" being the only third-party function that DHHS could license or authorize in the version of Section 74.36 then extant ("reproduce" and "distribute" not being third-party permitted functions)) is limited to *internal* government use. 815 F. Supp. at 1122. This interpretation is in harmony with the earlier discussion pointing out that permitting "use" outside the government is not within the bounds of "fair use."

NIH Response to Notice of Proposed Rule Making, http://www.grants.nih.gov/grants/policy/a110/nih-cmts.htm (emphasis added).[37] *Accord*, National Science Foundation Grant Policy Manual, § 732.2.b (July 2002) (federal purpose license "will not include the right to sell copies or photorecords of the copyrighted work to the public").

That "federal purpose" does not extend so far as to encompass broad, systematic public dissemination is further confirmed by DoD contract clauses which employ a "government purpose rights" regime for mixed (contractor and government) funding, such as DFARS 252.227-7013(b)(2) (Nov. 1995)(government purpose rights applied when technical data developed with mixed government and private sector funding). "Government purpose" is defined there as:

> *Any activity in which the United States is a party*, including cooperative agreements with international or multinational organizations, or sales or transfers by the United States Government to foreign governments or international organizations. *Government purposes* include competitive procurement, but *do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.*

DFARS 252.227-7013(a)(12)(emphasis added). *See also* Exec. Order No. 12591, 52 Fed. Reg. 13414, § 1.(b)(7) (Apr. 10, 1987), as amended by Exec. Order No. 12618, 52 Fed. Reg. 48661 (Dec. 24, 1987) (federal contractors to retain rights to data in exchange for royalty-free use *by or on behalf* of the government). By limiting the license to activities in which the government is a party, the authorized/licensed use under DFARS 252.227-7013(a)(12) is necessarily confined to government programs, and concomitantly excludes the type of broad public distribution envisioned by NIH's plan.

B. NIH'S PLAN WOULD INTERFERE WITH THE INTELLECTUAL PROPERTY PROVISIONS OF THE SMALL BUSINESS INNOVATION RESEARCH DEVELOPMENT PROGRAM.

The Small Business Innovation Development Act of 1982, Pub. L. No. 97-219 (codified, as amended, at 15 U.S.C. §§ 638 *et seq.*), establishes the Small Business Innovation Research ("SBIR") program. NIH is one of the largest federal participants in the SBIR program. NIH's plan would cover "all research grants" supported "in whole or part by NIH funding," presumptively encompassing SBIR grants and grantees. Special rules governing data rights, including copyrights, are applicable to small business under the SBIR program. The Act, at 15 U.S.C. § 638(j)(2)(A), grants small businesses under the SBIR program the right to "retain rights to data generated by the concern in the performance of an SBIR award for a period of not less than 4 years," which is reflected at FAR §§ 27.405(c) and 52-227-20(d) (during the 4 year period, government limited to government purpose rights (which exclude government

[37] The amendment to Circular A-110 was occasioned by the "Shelby Amendment" of 1998, Pub. L. No. 105-277, Div. A, § 101(h), 112 Stat. 2681-495. That amendment is implemented for DHHS agencies in 45 C.F.R. § 74.36(d).

procurement purposes)). "Rights to data generated by the concern in the performance of an SBIR award" include copyright. FAR § 52-227-20(b)(iv) & (c).

The U.S. Small Business Administration's ("SBA") policy guidance on the SBIR program expressly states that agencies cannot disclose SBIR technical data outside the government and must protect SBIR data from non-governmental use for the four-year period. SBA, Small Business Innovation Research Program Policy Directive, at § 8. Absent approval from SBA, inclusion of the SBIR data rights provisions in an award is mandatory and non-negotiable, *id.*, and agencies may not "diminish or remove" these rights during award administration, *id.*, and may not condition an award on modification of these rights, *id.*

NIH's stated intention to make researchers' manuscripts available to the public would effectively curtail the SBIR grantee's data rights, including copyright, when the manuscript is publicly disseminated by PMC. In virtually all circumstances, PMC publication will be well short of the four-year data rights grant of the SBIR Act. Accordingly, NIH's plan, absent approval from SBA, would interfere with the rights granted by the SBIR Act, as implemented by SBA's Program Policy Directive, subjecting the government to claims for copyright infringement under 28 U.S.C. § 1298(b) and for breach of grant terms and conditions.

C. NIH'S PLAN WOULD INTERFERE WITH TECHNOLOGY TRANSFER OF PATENTED INVENTIONS OWNED BY UNIVERSITIES AND OTHER NON-PROFITS UNDER THE BAYH-DOLE ACT AND UNDERMINE THE BAYH-DOLE PRINCIPLE THAT THE PUBLIC BENEFITS MORE WHEN INTELLECTUAL PROPERTY RIGHTS ARISING FROM FEDERALLY-FUNDED RESEARCH ARE HELD BY THE PRIVATE SECTOR RATHER THAN THE GOVERNMENT.

The Bayh-Dole Act of 1980, Pub. L. No. 97-219 (codified, as amended, at 35 U.S.C. §§ 200 *et seq.*) ("Bayh-Dole Act"), pertaining to patent rights and federally-funded research, applies to patents arising from NIH-funded research. NIHGPS, at 114-17. The Bayh-Dole Act permits NIH-sponsored research grantees that are small and not-for-profit entities to retain title to, and patent, inventions developed from the funded research. 35 U.S.C. §§ 200; 201(c); *see* Exec. Order No. 12591 (Apr. 10, 1987); 37 C.F.R. Part 401. The primary purpose of the Act is to expedite getting federally-funded technology to the marketplace. In exchange for title and associated patent rights to these inventions, grantees agree to pursue practical application of the inventions and to give the federal government a royalty-free, fully paid up license for government purposes. 35 U.S.C. § 202(c); FAR §§ 27.302(c), 52.227-11(b), -12(b) & -13 (c)(i). Prior to the Act, title to these inventions usually reverted to the federal government, in whose possession the inventions often languished and were not commercially marketed. By most accounts, the Act has been quite successful in its mission, and numerous universities and other non-profit institutions have played leading roles in the development of federally-funded technology.

NIH's plan has two significant, negative impacts on the Bayh-Dole approach. First, as NIH has recognized, one of the great challenges in translating basic research findings into drugs and patient therapies is technology transfer. Testimony of Mark L. Rohrbaugh, Ph.D, J.D., Director, Office of Technology Transfer, Office of the Director, National Institutes of Health,

Before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, July 10, 2003, *reprinted at* http://ott.od.nih.gov/NewPages/CT10Jul03.html. According to Dr. Rohrbaugh, technology transfer is "in its broadest sense . . . the movement of information and technologies from research findings to practical application, whether for further research purposes or commercial products." *Id*. at 2. Dr. Rohrbaugh further observed that: "At the NIH we *transfer technology through publications of research results*, exchange of data, sharing of materials, public private partnerships, as well as patenting and licensing technologies." *Id.* (emphasis added).

As Dr. Rohrbaugh recognized, publication of research results -- the fundamental work of the Associations' journals -- is a key mode of technology transfer of NIH-sponsored biomedical research from the findings stage to further research and commercial application. NIH's plan, which devalues the copyright interests of journals, will have the concomitant effect of negatively impacting technology transfer of research information that the Bayh-Dole Act seeks to expedite to the marketplace. In effect, the plan undermines the technology-transfer that the Bayh-Dole Act seeks to encourage. The result may well be significant lengthening of the technology transfer period, with adverse effects on federally-funded research.

This very phenomenon was experienced in the copyright arena by the Office of Education ("OE"), a division within the former Department of Health, Education and Welfare, between 1965 and 1970. In 1965 OE adopted a so-called "public domain" policy of prohibiting all copyright in OE-financed materials, only to reverse the policy in 1970 due to the policy's adverse effects on dissemination of research information. *See* Price, *Copyright in Government Publications: Historical Background, Judicial Interpretation and Legislative Clarification*, 74 Mil. L. Rev. 19, 54 (1976). From its experience during 1965-1970 with the "public domain" policy, OE learned that publishers would not edit and refine contract materials into a "publishable format" without a "guarantee that their product could not be copied by competitors":

> In short, the Office determined that a close alliance between contractors and private publishing houses was necessary to ensure the widest dissemination of materials created under OE contracts and grants, and thus make the most advantageous use of taxpayer money.

Id. at 55.[38]

The Bayh-Dole Act was enacted based on essentially the same principle that underlies permitting federal grantees to hold copyright, namely, that giving intellectual property rights to researchers is the best way to get the research to the public and the marketplace. 35 U.S.C. § 200; H.R. Rep. No. 96-1307(I), 96th Cong., 2nd Sess. (1980), *reprinted in* 1980 U.S.C.C.A.N.

[38] Under the 1970 change, OE gave authorization to grantees for copyright, subject to a license. *Id*. Although the Price article states that the legal basis for OE's copyright grant was "questionable," the 1970 OE change and Price's article itself precede enactment of the 1976 Copyright Act and OMB Circular A-110.

6460-61. Altering that principle with respect to copyright undermines the Bayh-Dole Act as well. In short, undercutting the copyright interests of federal grantees in order to support a government-run publisher model to distribute NIH-funded research risks undercutting the parallel principle applied to Bayh-Dole patent rights. This would be bad public policy as to copyright, just as it is as to patents.

NIH's plan also raises very real risks as to the preservation of patent rights, particularly foreign patent rights. U.S. law precludes patent protection after one year from the date an invention is disclosed in an unrestricted printed publication. 35 U.S.C. § 102(a). In those foreign countries that do not provide a grace period as does U.S. law, the patent application must be filed before any public disclosure, which means that the patents rights are immediately lost upon publication or other public disclosure if an application has not previously been filed. Under U.S. law, a document becomes a "printed publication" as of the date when those skilled in the relevant art are able to obtain sufficient access to the document. *See Constant. v. Advanced Micro Devices*, 848 F.2d 1560, 1568 (Fed. Cir. 1988); *Pfund v. United States*, 40 Fed. Cl. 313 (1998) (document is "printed publication" when abstract about the research article is published by the government). Two non-exclusive factors considered in determining "sufficient accessibility" are: (1) whether the document is "meaningfully indexed," and (2) actual dissemination of the document or intent to publish. *E.g., American Stock Exchange v. Mopex, Inc.*, 250 F.Supp. 2d 323, 330-31 (S.D.N.Y. 2003)*; In re Bayer*, 568 F.2d 1357, 1360-62 (Cust. & Pat. App. 1978). Placing just a single copy of a thesis in a college library in Germany has resulted in a "printed publication" because it was "meaningfully indexed." *In re Hall*, 781 F.2d 897 (Fed. Cir. 1986); *accord, E.I. du Pont de Nemours & Co. v. Cetus Corp.*, 1990 WL 305551, 19 U.S.P.Q.2d (BNA) 1174 (N.D. Cal. 1990) (National Science Foundation grant proposal indexed by title, author, institution and grant number in published index constitutes "printed publication" because it is publicly accessible under the Freedom of Information Act); *American Stock Exchange v. Mopex, Inc.*, 250 F.Supp. 2d 323, 330 (S.D.N.Y. 2003) (filing with the SEC constitutes "printed publication").

With respect to NIH's plan, accepted manuscripts submitted to PMC could well constitute "printed publications" under 35 U.S.C. § 102(a). *See E.I. du Pont de Nemours & Co. v. Cetus Corp.; accord*, Midgley, *The Freedom of Information Act: Another Pond for Prior Art Fishing Expeditions*, 27 AIPLA Q.J. 77 (Winter 1999). NIH's plan expressly envisions PMC archiving the manuscripts, Notification, which necessarily requires meaningful indexing. Upon depositing with PMC, the manuscripts become "agency records" under the Freedom of Information Act of 1966, Pub. L. No. 89-554 (codified, as amended, at 5 U.S.C. § 552)("FOIA"), and any person may access them unless a FOIA exemption applies. Under such circumstances, the manuscripts would be "printed publications" as of the date submitted to PMC. *E.I. du Pont de Nemours & Co.*, 1990 WL 305551 at n.7; Midgley, *The Freedom of Information Act: Another Pond for Prior Art Fishing Expeditions*, 27 AIPLA Q.J. at 92-101; *Mopex*. While this outcome arguably could be defeated by reliance on FOIA Exemption Four, 5 U.S.C. § 552(b)(4)(protecting confidential commercial information from FOIA disclosure), *see De Graffenried v. United States*; 16 U.S.P.Q.2d (BNA) 1321, 1329-32 (Ct. Cl. 1990) (document not a "printed publication" when cumbersome request procedure required), the U.S. Court of Appeals for the District of Columbia Circuit nonetheless has long held that information in federal research grant applications is *not commercial* in nature for purposes of FOIA. *Washington*

Research Project v. HEW, 504 F.2d 238 (D.C. Cir. 1974). Under the rationale of *Washington Research Project*, unpublished manuscripts concerning NIH-sponsored research would not be protected under FOIA Exemption Four, *id.*, and if not, they would constitute "printed publications" for purposes of U.S. patent laws.

Thus, the NIH plan could well alter the applicable time frame for preserving patent rights, possibly resulting in inadvertent loss of valuable patent rights. Researchers contemplating patenting inventions may not realize that manuscript submission to PMC will start the one-year clock under U.S. patent laws and/or cause the immediate loss of foreign patent rights, and thus fail to file timely patent applications prior to manuscript submission to PMC. This presents a very real risk with potentially disastrous consequences for grantees and researchers. NIH would also, at the least, suffer the loss of its license in the inventions. These risks weigh strongly against NIH's plan.

D. THE PLAN CONSTITUTES LEGISLATIVE RULEMAKING AND, BECAUSE NIH LACKS INDEPENDENT RULEMAKING POWER, NIH CANNOT ADOPT IT.

1. The Plan Constitutes Legislative Rulemaking.

Under the guise of announcing policy, NIH's plan formulates a legislative rule that is intended to have binding effect on individual rights and obligations.[39] This plan is not an interpretive rule or mere policy guidance. The plan's true character as a legislative rule can be discerned by looking to the four criteria articulated by the District of Columbia Circuit in *American Mining Congress v. Mine Safety & Health Administration*, 995 F.2d 1106 (D.C. Cir. 1993) and restated by Professor Richard Pierce in his authoritative treatise on administrative law, *Administrative Law Treatise*, § 6.4, at 345 (4th ed. 2000).

A rule is legislative if the answer to any one of the four "Pierce questions" is yes. First, in the absence of the rule, is there a lack of an adequate legislative basis for an enforcement action or other agency action to confer benefits or ensure the performance of duties? With respect to the plan, the answer quite obviously is "yes;" there is no legislative basis whatsoever to accomplish what the plan seeks to require. Second, is the preexisting legislative rule that the agency is claiming to interpret too vague or open-ended to support the interpretive rule/policy guidance? In the present instance, this criterion is inapplicable because NIH does not purport to interpret or offer policy guidance with respect to DHHS's copyright regulation, 45 C.F.R. § 74.36. Third, has the agency explicitly invoked its legislative rulemaking authority? This criterion likewise is not applicable because, for reasons to be discussed below, NIH has no legislative rulemaking authority to invoke. Fourth, does the "rule" at issue effectively amend a

[39] An agency's characterization of what it is purporting to do is not controlling. Rather, the substance and effect of the pronouncement is what matters. *See, e.g., Guardian Federal Savings & Loan Ass'n v. Federal Savings & Loan Ins, Corp.*, 589 F.2d 658, 666 (D.C. Cir. 1978); *American Frozen Food Inst., Inc. v. United States*, 855 F. Supp. 388, 396 (C.I.T. 1994) ("The court must focus on the intended legal effect of the rule adopted, not the stated intent of the agency, to determine whether a rule is legislative or interpretive."); *Saint Francis Memorial Hospital v. Weinberger*, 413 F. Supp. 323, 327 (N.D. Cal. 1975).

prior legislative rule? Here, the answer is most assuredly, "yes." The plan effectively will amend, indeed override, 45 C.F.R. § 74.36. The plan, therefore, is at bottom a legislative rule.

The foregoing conclusion is underscored, *inter alia*, by the plan's direct effect on the copyright rights of NIH grantees by limiting the effectiveness of their copyright as to manuscripts to six (6) months. These copyright rights are governed by DHHS's copyright regulation, 45 C.F.R. § 74.36, a substantive agency regulation having the force and effect of law affecting "individual rights and obligations," and which was adopted pursuant to the rulemaking provisions of the Administrative Procedure Act. *Respect, Inc. v. Committee on the Status of Women*, 815 F. Supp. 1112, 1124 (N.D. Ill. 1993). NIH has explicitly incorporated by reference 45 C.F.R. Part 74 in NIH's regulation governing grants, 45 C.F.R. Part 52a.8, and is bound by them. To alter such rights, governed by regulation, requires legislative rulemaking.

2. NIH Lacks Independent Rule-Making Power.

NIH has no independent rulemaking power; only the Secretary of DHHS may adopt legislative rules for NIH. Thus, NIH is limited to announcing interpretive rules and policy guidance, as illustrated by the NIHGPS. This is also the case as to the NLM, whose governing statute expressly reserves rulemaking as to NLM to the Secretary of DHHS ("Secretary"). 42 U.S.C. § 286.

NIH is an agency of the U.S. Public Health Service (PHS). 42 U.S.C. § 281 (a). The PHS is a component agency of DHHS. Reorg. Plan No. 3 of 1966, 31 Fed. Reg. 8855, 80 Stat. 1610, 42 U.S.C. § 202 note. While the NIH Director is appointed by the President and is subject to confirmation by the Senate, the NIH Director acts on behalf of the Secretary. 42 U.S.C. § 282(a) & (b).

Congress has not granted NIH or its Director independent rulemaking power as to grants or any other matter. Specifically, NIH's rules and regulations as to grants, 42 C.F.R. Part 52a, *et seq.*, are issued under the authority of the Secretary's rulemaking powers as to grants, 42 C.F.R. Part 52, which are in turn authorized by the Secretary's rulemaking powers derived from the PHS, 42 U.S.C. § 216. In like manner, Congress provided the Secretary, not the Director of NIH, with rulemaking authority as to the NLM. 42 U.S.C. § 286; *see* 42 C.F.R. Part 4. Finally, as previously noted, Circular A-110 precludes agencies such as NIH from departing from the uniform approach of Circular A-110 absent OMB approval, and to like effect is 45 C.F.R. § 74.3.

DHHS's supervisory role as to NIH is also acknowledged in NIH's Grants Policy Statement (NIHGPS) (Dec. 1, 2003):

> NIH, whose mission is to improve human health by increasing scientific knowledge related to disease and health, is an organizational component of HHS. NIH operates under the general policy guidance of the Department in carrying out its mission, which is accomplished through the conduct and support of biomedical and behavioral research, research training, research infrastructure, and communications.

. . .

> HHS develops, issues, and maintains regulations that govern the Department's grants process. Among these are the regulations that implement the OMB Circular A-102 common rule (applicable to grants to State, local, and Indian tribal governments) and OMB Circular A-110 (applicable to grants to institutions of higher education, hospitals, and other non-profit organizations). These regulations are codified at 45 CFR Part 74 (Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments, and Indian Tribal Governments) and 45 CFR Part 92 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments). They provide the framework for the terms and conditions of NIH awards as specified in Part II of the NIHGPS.

Id. Part I: NIH Grants – General Information, at 16.

Insofar as NIH may seek to find authorization for its actions in the language of House Report No. 108-636 (2004) dealing with fiscal 2005 appropriations, such justification is unavailing. Simply put, legislative history (*e.g.*, committee reports, debates, etc.) is not legislation. As the Supreme Court observed in *Tennessee Valley Authority v. Hill*, 437 U.S. 153, 191 (1978): "Expressions of committees dealing with requests for appropriations cannot be equated with statutes enacted by Congress . . . ." Legislative history cannot serve as the equivalent of an independent statutory source having the force of law when the statute that it accompanies is silent with respect to the matter at issue. If Congress does not enact a particular provision, an agency has no authority to enforce the equivalent of such a provision because it is found in the legislative history. *See, e.g., Shannon v. United States*, 512 U.S. 573, 583-84 (1994) ("We are not aware of any case . . . in which we have given authoritative weight to a single passage of legislative history that is in no way anchored in the text of the statute."); *Puerto Rico Department of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 501 (1988) ("[U]nenacted approvals, beliefs, and desires are not laws."); *In re Sinclair*, 870 F.2d 1340 (7th Cir. 1989) (statutory limitation of Chapter 12 bankruptcy provisions to prospective cases only could not be trumped by legislative history (a conference committee report) indicating an "intent" to extend the benefits of Chapter 12 to already commenced cases under Chapter 11); *International Brotherhood of Electrical Workers v. NLRB*, 814 F.2d 697, 712 (D.C. Cir. 1987) ("We believe that a cardinal principle of the judicial function of statutory interpretation is that courts have no authority to enforce principles gleaned solely from legislative history that has no statutory reference point."). *See also Hirschey v. FERC*, 777 F.2d 1, 7 n.1 D.C. Cir. 1985) (Scalia, J., concurring), *quoting* 128 Cong. Rec. 16918-19 (1982) ("[F]or any jurist, administrator, bureaucrat, tax practitioner, or others who might chance upon the written record of this proceeding, let me just make the point that this [referring to a conference report] is not the

law, it was not voted on, it is not subject to amendment, and we should discipline ourselves to the task of expressing congressional intent in the statute.").[40]

3. NIH May Not Regulate Beyond Its Statutory Power.

It is a bedrock principle of federal administrative law that an agency may not regulate in excess of its statutory authority. As put by the Supreme Court:

> The power of an administrative officer or board to administer a federal statute and to prescribe rules and regulations to that end is not the power to make law – for no such power can be delegated by Congress – but the power to adopt regulations to carry into effect the will of Congress as expressed by the statute. A regulation which does not do this, but operates to create a rule out of harmony with the statute, is a mere nullity.

Manhattan General Equipment Co. v. Commissioner of Internal Revenue, 297 U.S. 129, 134 (1936). *See also FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000); *Health Insurance Ass'n of America, Inc. v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994); *Killip v. Office of Personnel Management*, 991 F.2d 1564, 1569 (Fed. Cir. 1993*); Pender Peanut Corp. v. United States*, 20 Cl. Ct. 447, 455 (1990) (monetary penalty not authorized by statute cannot be imposed by regulation). Here, NIH is without any legislative rulemaking power. As the plan constitutes a legislative rule affecting substantive rights, NIH cannot adopt it, and to attempt to do so would amount to an *ultra vires* act.

The plan is also beyond NIH power as it is directly contrary to a DHHS regulation, 45 C.F.R. § 74.36 (applicable to NIH as discussed *supra*) and NIH cannot adopt a policy contrary to a controlling DHHS regulation. NIH is a component agency of the PHS and DHHS and acknowledges in the NIHGPS that: "HHS develops, issues, and maintains regulations that govern the Department's grants process." Part I: NIH Grants – General Information, at 16. Section 74.36 governs copyright policy as to grantees of DHHS's components, and the plan represents a policy contrary to Section 74.36. It has long been a cardinal principle of administrative law that an agency is bound to follow its own regulations, including those of its parent department. *See, e.g., United States v. Nixon,* 418 U.S. 683, 696 (1974); *Service v. Dulles*, 354 U.S. 363, 372, 383 (1957); *Ingram Barge Co. v. United States*, 884 F.2d 1400, 1405 (D.C. Cir. 1989); *Center for Auto Safety v. Dole, 828 F.2d 799, 809 (D.C. Cir. 1987); Bonita, Inc. v. Wirtz*, 369 F.2d 208, 212 (D.C. Cir. 1966) ("invalidation is necessitated in purely legal terms by reason of departure from the [agency's] own established rules"); *Sangamon Valley Television*

[40] The *Congressional Record* colloquy of September 8, 2004 between Representatives Istook and Regula concerning NIH's proposal is similarly devoid of any authoritativeness. Floor debates generally speaking, are suspect since they are nothing more than "expressi[ons] of the views and motives of individual members." *Duplex Printing Press Co. v. Deering*, 254 U.S. 443, 474 (1921). Such statements "cannot amend the clear and unambiguous language of a statute." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 457 & n.15 (2002). *See also United States v. Trans-Missouri Freight Ass'n*, 166 U.S. 290, 318 (1897).

Corp. v. United States, 269 F.2d 221, 224 (D.C. Cir. 1959) ("agency action that substantially and prejudicially violates the agency's rules cannot stand"). As NIH is a component agency of DHHS and lacks independent rulemaking power, NIH is subordinate to DHHS (and PHS) and cannot adopt a policy contrary to Section 74.36.[41]

E. THE NOTIFICATION IS INADEQUATE FOR LEGISLATIVE RULEMAKING.

Even assuming, for purposes of argument, that NIH possessed the requisite authority to promulgate the plan, the manner by which it is proceeding is legally deficient and runs afoul of the Administrative Procedure Act ("APA") requirements for informal rulemaking prescribed by 5 U.S.C. § 553. It is well established that an agency may not rely upon its "housekeeping" authority as embodied in 5 U.S.C. § 301 to issue regulations that speak to substantive rights and obligations of those being regulated. *See Schism v. United States,* 316 F.3d 1259, 1278-84 (Fed. Cir. 2002) (historical analysis of 5 U.S.C. § 301 and collection of authorities); *Respect, Inc*., 815 F.Supp. at 1125. Moreover, NIH may not rely on the APA exemption from notice and comment rulemaking set forth at 5 U.S.C. § 553(a)(2) for matters "relating to . . . public property, loans, grants, benefits, or contracts." DHHS has voluntarily waived the benefit of this exemption and consequently must follow the APA when regulating with respect to these topics. 36 Fed. Reg. 2532 (Jan. 28, 1971) (waiver by the Secretary of HHS and direction to all agencies within the department to utilize the rulemaking provisions of the APA when issuing rules and regulations relating, *inter alia,* to grants); *see Abbs v. Sullivan,* 756 F. Supp. 1172, 1188 (W.D. Wis. 1990); *Herron v. Heckler,* 576 F. Supp. 218, 229 (N.D. Cal. 1983).

As the plan constitutes legislative rulemaking, *see supra*, 5 U.S.C. § 553(b) requires that "general notice of the proposed rule making" be published in the Federal Register, and 5 U.S.C. § 553(c) requires an opportunity for comment by the public. The notice must include "either the terms or the substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). The notice of the proposed rule must be sufficient to permit the public to comment "meaningfully upon the agency's proposal." *Connecticut Light and Power Co. v. Nuclear Regulatory Commission*, 673 F.2d 525, 530 (D.C. Cir. 1982).

As these remarks indicate, the Notification fails to give the salient details of the plan, thereby denying the Associations and the public an opportunity to provide "meaningful" comment on many key aspects of the plan. The Notification does state that "NIH has established . . . a dialogue with publishers, investigators, and representatives from scientific associations and the public to ensure the success of this initiative."[42] The Notification, however, fails to provide

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[41] The plan is also beyond the scope of the Secretary's rulemaking power as to the NLM. Although the Secretary is authorized to prescribe rules for making NLM resources available to the public, 42 U.S.C. § 286, the plan would infringe on the copyright rights of grantees and their assignees as now provided under DHHS regulations and OMB Circular A-110. The Secretary has no power under 42 U.S.C. § 286 to adopt rules infringing on copyright or to compel NIH-sponsored grantees to submit materials to NLM.

[42] Consultations with interested parties does not obviate the need to adhere to APA requirements. *See USA Group Loan Services, Inc. v. Riley,* 82 F.3d 708, 714 (7th Cir. 1996).

any information as to this "dialogue" and whether it has relied upon data developed in the dialogue to reach decision concerning its plan. [43] If NIH has employed such data, it should have been identified and made available to the public in the Notification. As the D.C. Circuit has explained:

> To allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.

Id. at 530-31. *See also Home Box Office, Inc. v. FCC,* 567 F.2d 9, 35-36 (D.C. Cir. 1977) ("[T]he notice required by the APA, or information subsequently supplied to the public, must disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based.").

Therefore, should NIH seek to implement the plan, such action would be subject to invalidation for failure to have observed legislative rulemaking procedures. *E.g., Hoctor v. U.S. Department of Agriculture,* 82 F.3d 165 (7th Cir. 1996); *Jerri's Ceramic Arts, Inc. v. Consumer Product Safety Comm'n,* 874 F.2d 205 (4th Cir. 1989); *W.C. v. Bowen,* 807 F.2d 1502 ((9th Cir. 1987); *Batterton v. Marshall,* 648 F.2d 694 (D.C. Cir. 1980); *United States v. Zimmer Paper Products, Inc.,* 1989 WL 206586 (S.D. Ind. 1989); *American Academy of Pediatrics v. Heckler,* 561 F. Supp. 395 (D.D.C. 1983).

[43] NIH's Q and A also makes reference to the "dialogue" but does not identify what information was taken from the meetings. NIH Q and A, at question 15. The NIH Q and A also references a plan to "conduct a study" to evaluate the effects of the plan, but no details are given. *Id.* at question 12.

F. NIH'S PLAN CANNOT BE IMPLEMENTED ABSENT COMPLIANCE WITH THE REGULATORY FLEXIBILITY ACT.

Because the plan requires notice and comment rulemaking, *supra*, NIH must comply with the Regulatory Flexibility Act ("RFA"), Pub. L. No. 96-354 (codified, as amended, at 5 U.S.C. §§ 601, *et seq.*). The RFA requires that an agency first perform a regulatory flexibility analysis process and consider that analysis in its assessment of the plan before the plan may be promulgated as a final rule. *Id.*; *see* Exec. Order No. 13272 (Proper Consideration of Small Entities in Agency Rulemaking), 67 Fed. Reg. 53461 (Aug. 16, 2002) (OMB directive to facilitate compliance with the Regulatory Flexibility Act). The purpose of the RFA is to focus special attention on the impact of proposed agency actions on small entities through a public process by which the impact on small entities is assessed and alternatives considered by the agency. *See* 61 Fed. Reg. 27710, 27721 (1997); *National Ass'n for Home Care v. Shalala*, 135 F. Supp. 2d 161, 163-64 (D.D.C. 2001) (discussing purpose of RFA). *See also Associated Fisheries of Maine, Inc. v. Daley*, 127 F.3d 104, 111-14 (1st Cir. 1997) (discussing purpose and legislative history of RFA). To that end, the RFA requires an initial (and ultimately a final) regulatory flexibility analysis whenever an agency is required by law to publish a notice of proposed rulemaking. 5 U.S.C. § 603; *National Ass'n for Home Care*, 135 F. Supp. 2d at 163-64. The initial regulatory analysis is mandated by 5 U.S.C. § 603, which states in pertinent part:

> [W]henever an agency is required by section 553 of this title, or any other law, to publish general notice of rulemaking for any proposed rule …, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities. The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule.

Section §609(a) of title 5 further provides that "when any rule is promulgated which will have a significant economic impact on a substantial number of small entities, the head of the agency promulgating the rule . . . shall assure that small entities have been given the opportunity to participate in the rulemaking for the rule."

Where agency action is subject to the RFA, the agency must perform a final regulatory flexibility analysis in conformity with 5 U.S.C. § 604 before the final rule is promulgated. *See National Ass'n for Home Care,* 135 F. Supp. 2d at 163-64. A small entity that is adversely affected or aggrieved by the final agency action subject to the RFA is entitled to judicial review of the agency's compliance with the RFA. 5 U.S.C. § 611. Relief may include remand and deferred enforcement of the rule. *Id.; National Ass'n of Psychiatric Health Sys. v. Shalala,* 128 F. Supp. 2d 33, 43-45 (D.D.C. 2000) (finding Secretary "totally failed" to comply with RFA and remanding to DHHS for compliance).

Here, the Notification gives no cognizance to the RFA and there has been no separate indication that DHHS or NIH has initiated the procedures required by the RFA. Nonetheless, it is apparent that the RFA applies as the plan is an action proposed by an agency that requires

"general notice of rulemaking" under 5 U.S.C. § 553. DHHS is obviously an "agency" under the RFA, *see* 5 U.S.C. § 601(1); *National Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 43-46 (D.D.C. 2000), as is NIH.[44] As heretofore demonstrated, the plan requires notice and comment rulemaking and thus a "general notice of rulemaking for a proposed rule" is mandated. Nothing more is required to trigger the RFA.

Were the plan to be promulgated and/or implemented without RFA compliance, it would be subject to judicial challenge. 5 U.S.C. § 611 (providing judicial review of whether final agency action complies with RFA); *see e.g., National Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 43-46 (D.D.C. 2000). AAI and APS would be entitled to judicial review of DHHS's compliance (or non-compliance) with the RFA as the Associations constitute "small entities," as defined in the RFA, and they are adversely affected or aggrieved by the plan. Under the RFA, the term "small entities" encompasses "small business[es]," small organization[s]," and "small governmental jurisdiction[s]." 5. U.S.C. § 601(6). AAI and APS are "small organizations," as both are not-for-profit enterprises, independently owned and operated, and neither is dominant in its field.[45] The "adverse effects" of the plan on the Associations is demonstrated *supra*, and in any event, they are certainly "aggrieved" by the plan.[46] (Numerous other professional biomedical societies and their members would also qualify as "small entities" entitled to seek judicial review under the RFA.)

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[44] Per 5 U.S.C. § 601(1), under the RFA, "agency" means an "agency" as defined in 5 U.S.C. § 551(1), which covers each authority of the Government of the United States, whether or not it is within or subject to review by another agency (but excluding Congress, the Judiciary,

[45] "Small entities" under the RFA have the same meaning as the term "small organization" under 5 U.S.C. § 601(6). "Small organization" under that section is defined as "any not-for profit enterprise which is independently owned and operated and is not dominant in its field."

[46] The limited exemption contained in 5 U.S.C. § 605(b) (permitting agencies to avoid application of the RFA upon certification that the rule will not have a "significant economic impact on a substantial number of small entities") would not be applicable here. As discussed *supra* and in the AAI and APS separate comments, the plan would lead to a significant decrease in revenues for AAI, APS, and comparable non-profit associations and would adversely impact the Assocations' member/authors' economic interests in their copyright rights in their articles, all constituting "significant economic impact" on these numerous small entities. *See, e.g.,*. *Washington v. Daley*, 173 F.3d 1158, 1171 (9th Cir. 1999) (economic impact considered significant if the action resulted in more than a five (5) percent reduction in annual gross revenues); *North Carolina Fisheries Ass'n v. Daley*, 27 F. Supp.2d 650 (E.D.Va. 1998) (economic impact "significant" if agency action results in revenue loss of more than five (5) percent for 20 percent or more of the affected entities, or two percent of the affected entities cease operations.) The NIH Q and A contains an unsupported statement that NIH is "not aware the there will be a substantial impact" on scientific publishing. NIH Q and A, at question 12. Whatever weight this statement is entitled to is negated by NIH's subsequent revelation that it intends to do a "study to evaluate the effects of its policy[,]" *id*. and by the several references discussed in the text above indicating that NIH is very cognizant of the significant negative impact of its plan on scientific publishing.

Apart from forestalling a judicial challenge, an agency should undertake RFA compliance as a matter of good public policy. The evidence in this instance is overwhelming that the plan will have an adverse economic impact on professional biomedical associations and societies that publish peer-reviewed journals. Indeed, NIH's Notification acknowledges this very point in its discussion of the need to balance "free access" to NIH-funded research results against the "ability of journals and publishers" to "preserve their critical role" in biomedical publishing:

> The economic and business implications of any changes to the current paradigm must be considered as the NIH weighs options to ensure public access to the results of studies funded with public support without compromising the quality of the information provided.

Notification.

NIH also recognized this point in its May 2004 NIH Report to the House Appropriations Committee wherein it advised Congress of the substantial investment by scientific journals in their publications and the role of subscriptions in the traditional model, stating in pertinent part:

> The publication of refereed scientific journals involves a variety of costs associated with such things as reviewing, editing, publishing, and marketing. *Although electronic publication brings certain efficiencies and eliminates printing and mailing costs, the technical infrastructure required can be a substantial investment. Whether a journal is paper or electronic or both, publication costs must be covered in some way. The traditional publishing model in science has relied on subscriptions and advertising as major sources of revenue to pay these costs.*

May 2004 NIH Report, at 6 (emphasis added.) NIH also recognized the specific concerns of not-for-profit publishers of scientific journals (such as the Associations) with respect to the "open access model":

> Not surprisingly, the movement to an open access model has not been unconditionally embraced by all established publishers *who have concerns about the potential loss of subscriptions.* In the case of many *non-profit professional societies* revenues often are used to support other activities, such as scientific meetings, educational programs, and advocacy for research funding.

Id. at 9 (emphasis added). The Report's conclusion further conceded that paramount questions remain unanswered on key matters affecting the Associations:

> In spite of the appeal of wider access to federally supported research, moving to an open access model for dissemination of

> knowledge raises a number of questions. Will moving to open access require any change to the existing legal framework for current journal publications? Will it require changes in how such journals are financed? Will it impact the scientific peer-reviewed process or the high quality and reliability of the peer-reviewed published literature? *These questions remain.*

Id. at 11 (emphasis added).

These questions were unanswered in May 2004, remain unanswered today and are ignored in NIH's Notification.[47] Yet, they are precisely the type of questions and issues the RFA *requires* that agencies address prior to taking action, *see, e.g., National Ass'n of Psychiatric Health Sys.*, 120 F. Supp. 2d at 43-44, and which NIH *should want to answer*, as a matter of law and good public policy, before putting at risk the existing proven scientific publishing system and the infrastructure that supports it, by precipitously adopting the plan.[48]

G. THE PAPERWORK REDUCTION ACT APPLIES TO THE PLAN, AND ABSENT COMPLIANCE WITH THE ACT, ANY PENALTY IMPOSED UNDER THE PLAN IS INEFFECTIVE.

The Paperwork Reduction Act ("PRA"), Pub. L. No. 96-511 (codified, as amended, at 44 U.S.C. §§ 3501 *et seq.*), and its implementing regulations, 5 C.F.R. Part 1320, provide that a federal agency may not conduct or sponsor a "collection of information" unless the agency's information collection request has been subject to public comment and approved by the OMB. 44 U.S.C. § 3507(a); 5 C.F.R. Part 1320.5. *See generally Gossner Foods, Inc. v. Environmental Protection Agency*, 918 F. Supp. 359, 362 (D. Utah 1996) (in *dicta* noting that agency may not proceed with information collection absent compliance with the PRA).

NIH's plan is plainly a "collection of information" by an agency that is subject to the PRA. Again, DHHS, NIH and NLM are all obviously "agencies" under the PRA. 44 U.S.C. § 3502(1) ("any executive department . . . or other establishment in the executive branch"); 5 C.F.R. § 1320.3(a).

The plan's stated intention to "request" all NIH-sponsored grantees to submit final manuscripts to PMC constitutes an information "collection" as defined in 44 U.S.C. §

[47] Even NIH acknowledges the need for a "study" of the "effects of this policy." NIH Q and A, at question 12.

[48] The plan also is likely subject to the Congressional Review Act, 5 U.S.C. §§ 801-808 (requiring a report to Congress as to specified rule-makings likely to have an annual effect on the economy of $100 million or more, or a major increase in costs to federal agencies), and to Exec. Order No. 12866 (Regulatory Planning and Review), 58 Fed. Reg. 51735 (Sept. 30, 1993), *as amended by* Exec. Order No. 13258, 67 Fed. Reg. 9385 (Feb. 28, 2002)(requiring review of certain rules by OMB's Office of Information and Regulatory Affairs) and Exec. Order No. 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights), 53 Fed. Reg. 8859 (Mar. 15, 1988).

3502(3)(A) as it constitutes the "obtaining, causing to be obtained, or soliciting" of "facts or opinions by . . . an agency" that call for "identical reporting . . . requirements imposed on ten or more persons[.]" In like manner, submission of researcher manuscripts to PMC constitutes a "collection of information" as defined in 5 C.F.R. Part 1320.3, as it represents a "requirement or request for persons to . . . report or publicly disclose information."[49] Section 1320.3(c)(1) of 5 C.F.R. further states that a "collection of information" may be in "any form or format," specifically including, *inter alia*, "policy statements; plans; rules or regulations." Thus, irrespective of the legal or administrative nature of NIH's plan, it is covered under the PRA. *Cf. Dole v. United Steelworkers of America*, 494 U.S. 26, 38 (1990) (PRA does not apply to disclosure rules but noting in *dicta* that PRA does apply when agencies "gather information for their own use.").

Researcher manuscripts are PRA-covered "information" as PRA "information" includes "any statement . . . of fact or opinion, regardless of form or format, whether in . . . narrative form, and whether oral or maintained on . . . electronic media." 5 C.F.R. § 1320.3(h).[50]

Finally, the number of NIH-funded researchers certainly exceeds ten in number, but in any event, 5 C.F.R. § 1320.3(c)(4)(i) provides that any reporting requirement contained in a rule of general application, such as NIH's plan, is deemed to involve ten or more persons.

Because the PRA applies, NIH may not conduct or sponsor the instant collection of information unless it has, *inter alia*, conducted a review under the procedures of 44 U.S.C. § 3506(c)(1) and sought and considered public comment on the information collection prior to decision-making. 44 U.S.C. § 3507(b); 5 C.F.R. §§ 1320.5(a), 1302.6, 1320.7 & 1320.8. [51] Equally important, NIH must submit the information request to OMB and obtain approval of OMB. 44 U.S.C. § 3507(b). A key aspect of OMB's review will be a determination by OMB as to whether the information request is necessary for the proper performance of NIH's functions, 5 C.F.R. § 1320.5(e), an issue very much open to debate here.

Should DHHS (or NIH) conduct or sponsor the information collection without complying with the PRA, no person may be subject to any penalty for failing to respond to the collection of information. 5 C.F.R. § 1320.6(a); *see* 44 U.S.C. § 3512. *See also Dole v. United Steel Workers of America*, 494 U.S. 26, 40 (1990). The Notification, however, openly states that grantee

[49] It makes no difference whether the plan's manuscript submission request is deemed a "request" or a "requirement" as both mandatory and voluntary information collections are covered under the PRA. 5 C.F.R. § 1320.3(c) ("collection of information" included irrespective of whether "mandatory, voluntary or required to obtain or retain a benefit").

[50] The plan cannot avail itself of the "information" exceptions contained in 5 C.F.R. § 1320.3(h), such as affidavits, etc.

[51] Whether the agency collecting the information is considered to be DHHS, NIH or NLM is of no consequence as all three are covered by the definition of "conducting or sponsoring" the collection in this case. 5 C.F.R. § 1320.3(d). That section does contain a narrower definition of information collections *by* federal grantees; however, that provision is not applicable here as the plan intends a collection of information *from* federal grantees.

submission of manuscripts "will be monitored as part of the annual grant progress review and close-out process." NIH's threat, veiled though it may be, is nonetheless clear – NIH grantees failing to submit manuscripts could face adverse review, thereby affecting existing and future grant funding. Absent NIH compliance with the PRA, however, such action constitutes an impermissible and unenforceable penalty. *Id.*; 5 C.F.R. § 1320.3(j) ("penalty" encompasses agency "imposition" of "a fine or other punishment; . . . or revocation, suspension, reduction, or denial of a . . . grant or benefit"). *See generally Pacific National Cellular v. United States*, 41 Fed. Cl. 20 (1998) (upholding OMB regulations defining "penalty" even though term not defined in statute). Accordingly, neither DHHS nor NIH may take such action to force compliance with the plan.

H. NIH'S PLAN IS CONTRARY TO THE POLICY OF OMB CIRCULAR A-76 THAT FEDERAL AGENCIES SHALL RELY ON THE PRIVATE SECTOR, AND A COST COMPARISON STUDY IS REQUIRED BEFORE THE PLAN MAY BE IMPLEMENTED.

OMB Circular A-76, Performance of Commercial Activities (revised May 29, 2003) ("Circular A-76") sets forth federal policy to rely on the private sector for commercial services:

> The longstanding policy of the federal government has been to rely on the private sector for needed commercial services. To ensure that the American people receive maximum value for their tax dollars, commercial activities should be subject to the forces of competition. In accordance with this circular, including Attachments A-D, agencies shall:
>
> a. Identify all activities performed by government personnel as either commercial or inherently governmental.
>
> b. Perform inherently governmental activities with government personnel.
>
> c. Use a streamlined or standard competition to determine if government personnel should perform a commercial activity.

OMB Circular A-76, at § 4.

When an activity is determined to be a "new requirement," an "expansion" of a "commercial activity," or a "private sector activity," a cost comparison is required before the government may undertake it on an in-house basis:

> Before government personnel may perform a new requirement, an expansion to an existing commercial activity, or an activity

> performed by the private sector, a streamlined or standard competition shall be used to determine whether government personnel should perform the commercial activity.

Id. at § 5.d.

The publishing of professional journals by the Associations constitutes an "activity performed by the private sector" as defined in OMB Circular A-76. Indeed, NIH currently relies upon these private sector journals, which provide both hard-copy and electronic distribution, to disseminate peer-reviewed information concerning NIH-funded research. NIH and affiliated Federal agencies rely upon these private sector journals for current biomedical research information as they purchase subscriptions to professional journals, such as those of the Associations. Moreover, NIH grant funds partially fund publication costs through page charges.

A stated purpose of NIH's plan is to establish PMC as the "electronic resource of NIH-funded research results" and to make researchers' "final manuscripts" available "freely to the public through PMC." In other words, NIH wants PMC to become an in-house electronic publisher of these final manuscripts. This would patently result in government employees at NLM performing activities and services on an in-house basis that are now performed by the private sector journals.

Whether this aspect of the plan is considered a "new requirement," or an expansion of an "existing commercial activity," OMB Circular A-76, Attachment A, Part B (a "recurring service that could be performed by the private sector"), or conversion of an activity now performed by the private sector, the outcome is the same – NIH must perform a cost comparison study under OMB Circular A-76 before government personnel may undertake it. OMB Circular A-76, at § 5.d; *see Information Handling Services v. Defense Automated Printing Services*, 338 F.3d 1024 (D.C. Cir. 2003) (DoD decision to undertake in-house electronic publication of DoD standards and specifications represents new requirement, as compared to prior DoD hard-copy and fax distribution, and conversion of existing private sector activities to in-house production). Accordingly, NIH cannot implement its plan unless the agency performs a cost-comparison study and determines that its plan to have NIH distribute NIH-sponsored research results using accepted (but not final) manuscripts is less expensive to the federal government than the present system of scientific publishing.[52]

[52] The circumstances under which affected parties will have standing to challenge an agency's failure to comply with OMB Circular A-76 have been the subject of longstanding judicial debate. *Compare EEOC v. FLRA*, 744 F.2d 842 (D.C. Cir. 1984) (Circular A-76 was "applicable law" within meaning of 5 U.S.C. § 7106(a)(2)) *with National Federation of Federal Employees v. Cheney*, 883 F.2d 1038 (D.C. Cir. 1989) (union lacks standing to challenge Circular A-76 decision). For purposes of these comments, however, the Associations need not reach that point because compliance with Circular A-76 will be required by OMB in conjunction with the RFA and PRA processes.

V. CONCLUSION

For all of the foregoing reasons, NIH should abandon its plan and instead work cooperatively with the Associations and other publishers to determine how best to promote reasonable and sustainable policies to improve public access to science. Should NIH wish to discuss the foregoing comments, please contact us.

Respectfully submitted,

FOLEY & LARDNER

_____/s/_____
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Attachment: Agreement to Deposit Individual
Open Access Articles in NIH
PubMed Central Archive (4 pp.),
available at
http://www.pubmedcentral.nih.gov/about/openaccess.html/#singlearticle

ATTACHMENT 1

AGREEMENT TO DEPOSIT INDIVIDUAL OPEN ACCESS ARTICLES

IN NIH PUBMED CENTRAL ARCHIVE

Made this ____ day of _____ 200_, by and between the National Library of Medicine, National Institutes of Health (NIH), Department of Health and Human Services (hereinafter referred to as "NLM") and _____ (hereinafter referred to as "Participant").

WHEREAS, the NLM was established by statute in order to assist the advancement of medical and related sciences, and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, and, in carrying out this purpose, is authorized by statute to publish and make available its indexes and bibliographical listings, and to engage in other activities in furtherance of NLM's purpose (sections 465 and 466 of the Public Health Service Act, as amended (42 U.S.C. 286, 286a)); and

WHEREAS, one of the goals of the National Library of Medicine is to improve national health care through the delivery of information services; and

WHEREAS, Participant is willing to furnish electronically readable versions of selected full-text journal articles, at no expense to NLM, in order to incorporate this information into an online archive database at NIH, known as PubMed Central ("the PMC archive"), and thereby result in greater dissemination of biomedical information to scientists, physicians, other health science professionals and the public, which is consistent with NLM's statutory function to make biomedical information widely available; and

WHEREAS, Participant has agreed to grant NLM the above rights in accordance with the terms and conditions of this Agreement;

NOW THEREFORE, it is mutually agreed as follows:

1. Participant chooses to deposit in the PMC archive only articles that it publishes as open access articles, in conformance with the definition agreed to by the participants in the meeting on open access publishing (the "Bethesda Open Access" meeting) held at the Howard Hughes Medical Institute in April 2003. This definition is reproduced in paragraph 16 of this Agreement.

2. Participant agrees to deliver to NLM an electronic version of these full-text journal articles in SGML or XML format. The full-text SGML or XML must conform to either the NLM Journal Publishing XML DTD or the Keton SGML DTD. If a PDF version of the article exists, it shall be submitted in addition to the SGML/XML files. Figures, photographs, and other graphic material shall be included in high-resolution TIFF or EPS format or, where these are unavailable, in JPEG or GIF format. Any supplementary material such as video, sound, datasets, or software, that is available with the article at the journal's site shall also be delivered. (All the above forms of data are hereinafter referred to collectively as the "Material.") NLM shall be able to generate a printable view for user presentation, e.g., HTML, from the submitted SGML/XML. All

Material submitted to NLM may be exchanged freely with collaborating mirror sites of PubMed Central.

3. Participant shall furnish, in paragraph 15, a list of the journals from which open access articles will be deposited in PubMed Central. As a condition of inclusion in PubMed Central, each journal must be indexed in one of the major abstracting and indexing services such as MEDLINE, BIOSIS, EMBASE, Science Citation Index, PsychINFO, Agricola or Chemical Abstracts. In lieu of this, at least three editorial board members must currently be principal investigators on research grants from major funding agencies in order for any journal to be included in PubMed Central. All journal titles submitted must have peer review of their respective scientific content.

4. The journal shall deposit all the Material for an article in PMC on or before the date of publication. The deposited files must conform to PMC's standard file specifications and must meet PMC's data quality standards for complete and accurate content.

5. Material deposited in the PMC archive will be retagged if necessary, by NLM, to conform to the NLM XML DTD format used for all data in the archive. When the Material is included in the archive, NLM shall index the full text and use such indexes to provide free access via the World Wide Web to online searching of the archive and linking of the full text with related resources including, but not limited to, gene sequence data, whole genomes and online text books.

6. NLM and NLM's users will have all the rights to distribute or use the Material as specified in the definition of an open access publication in paragraph 16.

7. Full text of these articles will be displayed in the same way as standard PMC articles, except that NLM is not required to display the contributing journal's logo on the full-text article page in PMC, or to provide links from this page in PMC to the journal site, or to display a separate Table of Contents page for the journal.

8. NLM shall:

- clearly indicate to users of PubMed Central the identity of the source of each submitted article and that copyright in each article belongs to the respective authors or to Participant or its licensors, whichever is stated in the SGML/XML-tagged version of the full-text article supplied to PMC;
- assist in the submission process of SGML/XML tagged content;
- coordinate with the repository efforts of international partners;
- archive the content and provide that the content will remain accessible in the future to the Participant and other users of PubMed Central whether or not this Agreement is still in effect;
- comply with any request of Participant for a copy of the originally submitted data files whether or not this Agreement is still in effect.

9. NLM represents that the PubMed Central software developed by NLM was prepared with a reasonable standard of care. NLM makes no representations or warranties, expressed or implied, regarding the accuracy of the software or that the software is error-free.

10. NLM is not limiting the number of Participants in the PubMed Central project beyond restricting the journal articles to the domain of the life sciences and related disciplines as defined by NLM and subject to the submission conditions in paragraph 2 above.

11. In its system documentation and online help files, NLM shall acknowledge Participant as the source of the journal material. The use of this Material does not imply an endorsement by NLM of the Participant or its data. NLM makes no representation or implied warranty of merchantability or fitness for a particular purpose with respect to the NLM database and NLM specifically disclaims any such warranties and representations.

12. NLM's rights to use the Material under this Agreement are nonexclusive. NLM acknowledges that it does not assert any copyright over the Material submitted and that copyright resides with the Participant and/or the authors of the respective journal articles, whichever is applicable. NLM shall provide notice in its system documentation and online help files that users should be aware that Material in the databases may be from copyrighted sources. Participant shall indemnify NLM from and against any and all expenses, damages or loss from any claim by any person or entity arising from any intentional or negligent acts or omissions or copyright infringement on the part of Participant. NLM shall not be liable for any claims, demands, damages, expenses or losses arising from its use of the Material under this Agreement. NLM shall provide notice that users of the database are solely responsible for compliance with copyright restrictions. In consideration of this notice, Participant shall hold NLM harmless from any liability for any intentional or negligent acts or omissions or copyright infringement on the part of users of the database.

13. This Agreement shall be effective for one year from the date first written above and shall be automatically renewable for further one year periods unless either party provides written notice of its intention not to renew at least 30 days in advance of the renewal date. Either party may terminate this Agreement at any time for any reason upon 30 days written notice to the other party, without liability to the other party.

14. In the event of termination of this Agreement by Participant, all Material supplied to PMC by Participant prior to the date of termination will be retained in the PMC archive. NLM's right to display the full text of Participant's Material retained in PMC after the date of termination shall not change.

15. Participant may deposit individual open access articles from the following journals in PubMed Central:

A.

16. An Open Access Publication[1] is one that meets the following two conditions:

- The author(s) and copyright holder(s) grant(s) to all users a free, irrevocable, worldwide, perpetual right of access to, and a license to copy, use, distribute, transmit and display the work publicly and to make and distribute derivative works, in any digital medium for any responsible purpose, subject to proper attribution of

authorship[2], as well as the right to make small numbers of printed copies for their personal use.

- A complete version of the work and all supplemental materials, including a copy of the permission as stated above, in a suitable standard electronic format is deposited immediately upon initial publication in at least one online repository that is supported by an academic institution, scholarly society, government agency, or other well-established organization that seeks to enable open access, unrestricted distribution, interoperability, and long-term archiving (for the biomedical sciences, PubMed Central is such a repository).

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[1] Open access is a property of individual works, not necessarily journals or publishers

[2] Community standards, rather than copyright law, will continue to provide the mechanism for enforcement of proper attribution and responsible use of the published work, as they do now.

IN WITNESS WHEREOF, the parties have executed this Agreement, effective upon the date first written above:

B. NATIONAL LIBRARY OF MEDICINE

C. PARTICIPANT

Signature	Signature
Kent A. Smith Name	Name
Deputy Director, NLM Title	Title