Before the
Office of Management and Budget
Washington, D.C. 20503

In the Matter of	)
	)
Draft Joint Report on the Review of the	)
Application of European Union and United States	)
Regulatory Impact Assessment Guidelines on the	)
Analysis of Impacts on International Trade and	)
Investment	)

The Association of American Publishers and The Washington DC Principles for Free Access to Science Comments on Joint U.S. OMB-European Commission Proposal on Analysis of Impacts of Regulation on International Trade

I. AAP AND DC PRINCIPLES COMMEND OMB FOR PROPOSING ANALYSIS OF IMPACT OF REGULATION ON INTERNATIONAL TRADE AND INVESTMENT

The Association of American Publishers ("AAP") and The Washington DC Principles for Free Access to Science ("DC Principles") submit these comments to encourage the Office of Management and Budget ("OMB") to provide guidance to federal agencies on analyzing the impact on the international trade and investment of proposed rules. On November 8, 2007, OMB and the Secretariat General of the European Commission issued a Draft Joint Report for Comment entitled *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment* ("Draft Joint Report").[1] The Draft Joint Report reviews the application of OMB's Circular A-4 with the goal of ensuring that assessment of future regulations takes due account of their impacts on international trade and investment.[2] The Draft Joint Report was prepared as part of the dialogue between the European Commission and OMB as agreed in the *Framework for Advancing Transatlantic Economic Integration between the European Union and the United States of America* ("*Framework*") of April 2007. Many members of the AAP have operations in Europe as well as the United States, and many members of the DC Principles have European counterpart societies in their particular discipline – and all have significant trading relationships with the United States and Europe. The AAP and the DC Principles therefore support the *Framework* goals generally, and, more specifically, support

[1] *See* Draft Joint Report on the Review of the Application of European Union and United States Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment, 72 Fed. Reg. 69719 (Dec. 10, 2007).

[2] *Id.*

interpreting OMB Circular A-4 to require agency analysis of a rule's impact on international trade and investment.

The AAP is composed of over 330 publishers, including corporations, not-for-profit associations, and university presses. The AAP's objectives include expanding the market for American books and other published works in all media; promoting the status of publishing in the United States and throughout the world; nurturing creativity by protecting and strengthening intellectual property rights, especially copyright; and fostering public understanding of the unique value published materials have in the cultural and political life of our nation. The DC Principles is composed of the nation's leading not-for-profit medical and scientific societies. With over 75 not-for-profit society publisher members, the DC Principles works in partnership with scholarly communities to ensure that these communities are sustained and extended. The DC Principles' objectives are that science is advanced, research meets the highest standards, and patient care is enhanced with accurate and timely information, including through broad access to the scientific and medical literature.

The AAP and the DC Principles are active in a sector that many call scientific, technical and medical ("STM") publishing. Approximately 1,000 U.S.-based STM publishers employ some 30,000 staff and indirectly support an additional 20,000 workers. The U.S. STM market represents some $7-8 billion in annual revenue, of which journals comprise about $3 billion. The global market for English-language journals is approximately $7 billion.[3] North America-based STM publishers account for 45% of all peer-reviewed manuscripts published annually for researchers worldwide. European STM publishers account for approximately 40% of the global STM employee base, or 36,000. So, today U.S.-based publishers are significant employers and competitive in the global market, but that position is being challenged. The output factor of articles from publishers located within the European Union ("EU") grew faster than the U.S. in the late 1990s.[4] The competitiveness of the EU's articles improved as well. In the five years between 1998 and 2003, the EU's share of global journal article citations increased significantly, to some extent closing the gap with U.S. journals.[5] But the most dramatic growth is in the output of articles from the East Asia region, including China, Taiwan, Singapore and South Korea.[6] The growth in article output for China and its East Asia neighbors has been around 15% over the period, compared to 1-2% growth for the U.S.[7] As the National Science Foundation has noted, non-U.S. and non-English speaking

[3] *See* Mark Ware Consulting Ltd., Scientific Publishing in Transition: An Overview of Current Developments 6-8 (2006) ("*Scientific Publishing Overview*").

[4] *Id.* at 8.

[5] *Id.* at 10.

[6] *See* Derek Hill et al., National Science Foundation, Changing U.S. Outputs of Scientific Articles: 1988–2003, Special Report 7-19 (2007).

[7] *Scientific Publishing Overview* at 8.

scientists are improving, and are publishing more articles in journals and therefore represent increasing competition.[8]

Subscriptions account for approximately 90% of revenue for many journal publishers. That revenue underwrites critically important publishing functions including managing the peer-review system that is essential to quality control and fostering scientific excellence; preparing articles for publication; hosting articles online and disseminating them; and preserving authors' work as part of the permanent scientific record. Subscriptions ensure that researchers can submit their articles to the journals of their choice and that there are no financial deterrents or incentives that would undermine the independence and integrity of their published work. The importance of subscription revenue is true for not-for-profit publishers as well, such as the members of the DC Principles. Not-for-profit publishers rely on subscription revenue for programs supporting their member scientists, both professional and student researchers, and educating the public.

II. SCIENTIFIC, TECHNICAL AND MEDICAL PUBLISHING IS AN INCREASINGLY INTERNATIONAL MARKET.

The AAP and the DC Principles applaud OMB and the European Commission's joint report proposing guidance to agencies for the purpose of analyzing the impact of proposed regulation on international trade and investment. The STM industry is becoming more globalized, due to a variety of factors. Scientific research is becoming more international and more collaborative, driven by lower costs of air travel and international telephone calls, increased use of information technology, national policies encouraging international collaboration, and graduate student study abroad programs.[9] Cross-national citations of STM journals, where an article authored by a researcher in one country is cited by a researcher in another country to support his arguments without restating the earlier work in detail, has increased dramatically over the last two decades.[10] This globalization of scientific research has contributed to a more international market for U.S.-based publishers' STM journals.

The AAP and the DC Principles therefore support OMB's proposal to require agencies to analyze international impacts. The AAP and the DC Principles additionally propose that such international trade and investment review include analysis of the impact of the proposed regulation on the cross-border supply and consumption of U.S. goods and products abroad. Publishers also propose that before an agency adopts a rule, it undertake a cost-benefit analysis that includes the impact of the rule on U.S. competitiveness in the relevant international market. Total global readership of scientific journals is approximately 12-15 million readers.[11] U.S. publishers of biomedical journal

---

[8] Robert K. Bell, SRS Publication Trends Study 4-6 (2007) *available at* http://www.nsf.gov/statistics/nsf07330/pdf/nsf07330.pdf.

[9] *Scientific Publishing Overview* at 9.

[10] *Id.* at 10.

[11] *See id.*

articles in the aggregate obtain more than 50% of the revenues from international markets. Understanding the international impacts of a rule impacting cross-border supply and consumption abroad of U.S. journal articles is critical for the continued competitiveness of the U.S. STM publishing industry.

III. ANY U.S. REGULATION THAT REQUIRES POSTING CONTENT ON THE INTERNET WILL HAVE AN IMPACT ON CROSS-BORDER SUPPLY AND CONSUMPTION OF U.S. CONTENT ABROAD AND SHOULD REQUIRE INTERNATIONAL IMPACT ANALYSIS.

The majority of STM articles are now on-line, primarily due to the policies of the U.S. and European publishing industry.[12] U.S. and European publishers have invested millions in information technology infrastructure to enhance access to their articles. Any U.S. regulation that relates to posting content on the Internet will have an inherent impact on cross-border supply and consumption of U.S. content abroad and should require international impact analysis.[13] Such analysis should include analysis of the impact on revenues for U.S. providers of products consumed abroad, like STM articles. For instance, the National Institutes of Health ("NIH") recently required researchers it funds in part or completely to submit final peer-reviewed manuscripts that have been accepted for publishing to it for posting to NIH's on-line PubMed Central ("PMC") database, which is available on the Internet.[14]

Once on the Internet, after a 12 month embargo, such manuscripts are available for free access, review and downloading by readers all over the world. Moreover, NIH intends to mirror its PMC postings on the UK PMC repository, further extending the targeted, free on-line reach of U.S. manuscripts. UK PMC can also be expected to "enhance" the manuscripts, which will provide further, government-funded (and in the UK example, foreign-government funded[15]) competition to the U.S. STM industry. NIH is also planning to mirror its postings to other international repositories, when and if they come on-line, with publishers' permission being required. This approach will clearly have an impact on cross-border supply of U.S. STM articles, and on U.S. publishers' revenues from consumption abroad. Given the increasing degree of cross-national

---

[12] *Id.* at 8.

[13] *See* Press Release, Association of American Publishers, Publishers Say Enactment of NIH Mandate on Journal Articles Undermines Intellectual Property Rights Essential to Science Publishing (Jan. 3, 2008) ("'Journals published in the U.S. have strong markets abroad; indeed, in some fields of research, most sales are to institutions and individuals outside the United States,' Adler said. 'A government policy requiring these works to be made freely available for international distribution is inherently incompatible with the maintenance of global markets for these highly successful U.S. exports. Smaller and non-profit scientific societies and their scholarly missions will be particularly at risk as their journal subscribers around the world turn to NIH for free access to the same content for which they would otherwise pay.'").

[14] National Institutes of Health, Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, NIH Notice Number NOT-OD-08-033 (Jan. 11, 2008) ("NIH Mandatory Public Access Rule") *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html.

[15] UK PMC is partially funded by UK government entities and operated by a number of organizations funded by non-U.S. governments. *See* http://ukpmc.ac.uk/ppmc-localhtml/about.html.

citation in STM articles, and the global readership, the on-line posting policy will also have an impact on European publishers as well. It is not surprising that when NIH first sought comment on a proposed voluntary PMC posting policy in 2004,[16] it received substantial support for free, on-line access to the manuscripts from librarians and foreign researchers.[17]

IV. ANALYSIS SHOULD LIKEWISE INCLUDE WHETHER DOMESTIC REGULATION IS INCONSISTENT WITH U.S. COMMITMENTS UNDER INTERNATIONAL AGREEMENTS OR POSITIONS IN INTERNATIONAL TREATY ORGANIZATIONS, SUCH AS WTO AND WIPO.

An important aspect of any agency review of a proposed rule should be its compliance with U.S. treaty obligations. This is true as well with respect to the STM industry, where international treaties administered by the World Intellectual Property Organization ("WIPO") govern the treatment of copyrighted works. The U.S. is a signatory of the Berne Convention for the Protection of Literary and Artistic Works, which requires a signatory to recognize the copyright of works of authors from other signatory countries in the same way it recognizes the copyright of its own nationals. Likewise, the U.S. is a party to many multilateral and bilateral trade agreements that obligate signatories to protect copyrighted works, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") within the World Trade Organization ("WTO"), and scores of bilateral investment treaties and other free-trade agreements ("FTAs") that have TRIPS-based chapters on intellectual property rights protection. A proposed rule that requires a U.S. agency to universally force all agency-funded grantees to submit their manuscripts for posting on the Internet, when the journal article is copyrighted by a publisher, may be inconsistent with U.S. commitments in WIPO, WTO, and many FTAs.

Moreover, such a rule, without adequate analysis, may impact U.S. negotiators' ability to press trading partners on adequate copyright and other intellectual property enforcement. The AAP and the DC Principles note that the Administration already has publicly supported studying the impact of the NIH mandatory policy, including on "the United States' longstanding leadership in upholding strong standards of protection for intellectual property."[18] Formalizing an international-impacts analysis within agencies

---

[16] Enhanced Public Access to National Institutes of Health (NIH) Research Information, 69 Fed. Reg. 56074 (Sept. 17, 2004).

[17] NIH's webform by which it sought comment in 2004 on NIH-funded researchers submitting their final peer-reviewed manuscripts for posting on-line at PMC did not require commenters to state their name or employer. Based on what data was provided, publishers deduced that the majority of support for free on-line access after a 12 month or less delay was from librarians and foreign researchers. Any notice and comment process that includes an analysis of impact on international trade and investment should require commenters to state their name, employer, and country of residence, so as to permit the reviewing agency to adequately weigh the international trade and investment interests at issue.

[18] *See* Office of Management and Budget, Statement of Administration Policy: S. 1710 – Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 at 5-6 (Oct. 17, 2007) *available at* http://www.whitehouse.gov/omb/legislative/sap/110-1/s1710sap-s.pdf.

might better protect against inadvertently overlooking the effect of one agency's rule on the position of another agency relative to international trade and investment negotiations.

V. AAP AND DC PRINCIPLES SUPPORT THE DRAFT JOINT REPORT PROPOSAL TO REQUIRE AGENCIES TO CONSIDER HOW PROPOSED REGULATIONS WILL IMPACT INTERNATIONAL TRADE AND INVESTMENT.

The AAP and the DC Principles agree with the Draft Joint Report that in an increasingly global marketplace, regulatory analysis must increasingly consider the impact of regulations on international trade and investment. This international impact analysis, moreover, builds upon the foundational requirements for sound regulatory policymaking in the United States.

As the Draft Joint Report explains, "regulatory agencies have an obligation . . . to show that their rules have a sound reasonable basis."[19] In particular, international impact assessments should be incorporated into a transparent set of rules, accessible to the public, that is the product of "public consultation and notice and comment mechanisms in place that give[s]" all interested parties the opportunity to voice their support or concerns.[20] And per OMB Circular A-4, the need for analysis of proposed regulatory actions applies to all regulatory actions, whether or not formally proposed as rules.[21] These principles – principles integral to policymaking in the public interest – are reflected in features of the existing U.S. regulatory regime, including the requirements of the Administrative Procedure Act ("APA"), and Executive Orders 12866 (as implemented by OMB Circular A-4).

A. Notice and Comments Requirements of the APA.

The APA requires that agencies engaged in legislative rulemaking provide "general notice of the proposed rule making" in the Federal Register.[22] In so doing, the agency must "give interested persons an opportunity to participate in the rule making" and give "consideration [to] the relevant matter presented."[23] Upon publishing the final rule, "the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose."[24]

The APA defines a "rule" broadly as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy

---

[19] Office of Management and Budget and the Secretariat General of the European Commission, *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment*, Draft Joint Report 10 (2007) ("Draft Joint Report").

[20] *Id.* at 25.

[21] Office of Management and Budget, Circular A-4 at 1, n. 1 (Sept. 17, 2003) ("OMB Circular A-4").

[22] 5 U.S.C § 553(b).

[23] *Id.* § 553(c).

[24] *Id.*

or describing the organization, procedure, or practice requirements of an agency."[25] But only "substantive" (also called "legislative") agency rules must meet the Act's notice, comment and publication requirements before final implementation, while "interpretative rules" are not subject to these requirements.[26] While courts have applied various tests to distinguish the two types of rules, in essence, "legislative rules" are those that create law, usually implementing existing law or imposing general, extra-statutory obligations pursuant to authority properly delegated by Congress, while "interpretive rules" merely clarify or explain existing law or regulations.[27]

By its terms, the APA also exempts agency grants from these notice and comment requirements.[28] Specifically, section 553(a)(2) provides that the requirements do not apply to matters "relating to agency management or personnel or to public property, loans, grants, benefits, or contracts."[29] Recognizing the importance of these procedures to good decision making, however, agencies, including the predecessor to the Department of Health and Human Services, which overseas the U.S. Public Health Service and NIH, have waived this exemption.[30] Specifically, the Department directed "all agencies and offices of the Department which issue rules and regulations relating to . . . grants . . . to utilize the public participation procedures of the APA, 5 U.S.C. § 553."[31] As the agency explained, the "public benefit" from the "greater participation by the public in the formulation of this Department's rules and regulations" would "outweigh any administrative inconvenience or delay."[32]

The increasingly international impacts of agency rulemakings only enhance the importance of the APA's notice and comment procedural protections. As the Draft Joint Report explained, "it is crucial to have public consultation and notice and comment mechanisms in place that give the authorities, businesses, and citizens of the EU, U.S. and third countries the opportunity to voice solicited or unsolicited comments on planned initiatives, and to reflect their input in impact assessment and impact analysis reports."[33] The AAP and the DC Principles could not agree more.

---

[25] *Id.* § 551(4).

[26] *See Guadamuz v. Bowen*, 859 F.2d 762, 771 (9th Cir. 1988). *See* 5 U.S.C. 553(b)(3)(A) (exempting "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" from section 553 requirements).

[27] *Southern California Edison Co. v. Federal Energy Regulatory Comm'n.*, 770 F.2d 779, 782-3 (9th Cir. 1985).

[28] 5 U.S.C. § 553(a)(2).

[29] *Id.*

[30] Public Participation in Rule Making, 36 Fed. Reg. 2532 (Feb. 5, 1971).

[31] *Id. See also Abbs v. Sullivan*, 756 F. Supp. 1172, 1188 (W.D. Wis. 1990), judgment vacated on other grounds, 963 F.2d 918 (7th Cir. 1992) (applying the HHS waiver to NIH policy).

[32] Public Participation in Rule Making, 36 Fed. Reg. at 2532.

[33] Draft Joint Report at 25.

B. Regulatory Analysis Requirements of Executive Order 12866 and OMB Circular A-4

Independent of the APA's requirements, significant agency actions, including agency guidance documents, must comply with regulatory planning and review requirements set out in Executive Order 12866 and OMB's related circulars and bulletins. Executive Order 12866 continues a tradition of regulatory oversight that began nearly three decades ago and has remained a key feature of both Republican and Democratic administrations since then. The order opens by stating that:

> The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory polices that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable.[34]

The basic purpose of Executive Order 12866 is to guard against unnecessary or inefficient government regulation and to ensure agency consistency with Presidential priorities and the actions of other agencies. It directs agencies to conduct regulatory analysis of significant economic regulatory actions – those resulting in a rule that may "have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy" as well as "significant regulatory actions," which includes those that may "materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof."[35] OMB Circular A-4 guides agencies' regulatory analysis of such actions. Specifically, agencies must identify the market failure or other systemic problem they intend to address, assess the costs and benefits of alternative regulatory solutions (including not issuing a regulation), and select the approach that maximizes the net benefits.[36] Even where Congress has established a regulatory program, "regulations should be examined to ensure that they are both effective and cost-effective."[37]

Recently, the Bush Administration amended Executive Order 12866, issuing Executive Order 13422, accompanied by the OMB Bulletin on Good Guidance Practices,[38] which extended many of these principles of sound regulatory analysis to

---

[34] Exec. Order No. 12866, 58 Fed. Reg. 51735 (Sept. 30, 1993) (as amended by Exec. Order No. 13258 (Feb. 26, 2002) and Exec. Order No. 13422 (Jan. 18, 2007)).

[35] *Id.* § 3(f), 58 Fed. Reg. at 51738.

[36] *See* OMB Circular A-4 at 10.

[37] *Id.* at 5.

[38] *See* Office of Management and Budget, Final Bulletin on Good Guidance Practices, Bulletin 07-02 (2008) ("Bulletin") *available at* http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf.

agency guidance documents. These new requirements are intended to ensure that agency guidance documents will be of "high quality, developed with appropriate agency review and public participation, and be readily available to the public."[39] Specifically, guidance documents, like regulations, shall be "based on the best reasonably obtainable scientific, technical, economic and other information" and shall be tailored "to impose the least burden on society . . . taking into account . . . the cost of cumulative regulations."[40] While agencies are not required to undertake a comprehensive cost-benefit analysis for guidance documents, agencies must provide the public with notice and an opportunity to comment and a written document responding to comments for "economically significant guidance documents" – those that may reasonably be anticipated to lead to an annual economic effect of $100 million or greater.[41]

As the Draft Joint Report correctly notes, however, these executive orders "do not offer clear guidance on how to consider the international trade and investment effects of U.S. regulation."[42] Given the increasingly international nature of the economy, as exemplified by the globalization of the STM industry, the AAP and the DC Principles believe that such guidance is necessary to ensure that rules and guidance documents maintain the quality, transparency, accountability, and coordination that have proven so crucial to sound policymaking. In particular, the AAP and the DC Principles believe an agency should demonstrate the need for any proposed regulation that might impede international trade and investment and analyze the international effects of such regulations, including their effects on consumption abroad of U.S. products and their consistency with U.S. commitments and positions in international fora.

VI. APPLICATION TO NIH MANDATORY PUBLIC ACCESS RULE.

While the AAP and the DC Principles support OMB's efforts to provide guidance to agencies for analyzing the international impact of all significant regulations, we highlight here a specific example of the benefit of international impact analysis relating to NIH's Mandatory Public Access Rule. As mentioned above, in January 2008, the NIH issued its Mandatory Public Access Rule, which requires researchers to submit to NIH's publicly accessible database all peer-reviewed manuscripts that arise, in whole or in part, from funds granted by NIH. NIH took this action, which will have an economic impact on STM publishing well in excess of $100 million, without any notice, public comment, or regulatory analysis. This example demonstrates the importance of and need for additional OMB guidance that will instruct agencies to conduct the necessary regulatory analysis of proposed regulations, including an analysis of their impact on international trade and investment.

---

[39] Memorandum from Susan E. Dudley, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, to Regulatory Policy Officers (Apr. 25, 2007) ("Dudley Memorandum") *available at* http://www.whitehouse.gov/omb/memoranda/fy2007/m07-13.pdf.

[40] *See* Exec. Order No. 12866 §§ 1(b)(7), (11), 58 Fed. Reg. at 51736.

[41] Bulletin §§ I(5), IV(2); Dudley Memorandum at 3, 5.

[42] Draft Joint Report at 11.

Announced just last month, the NIH Mandatory Public Access Rule requires scientists to submit peer-reviewed journal manuscripts that arise from NIH funds to the digital PMC database, which is publicly available on the Internet.[43] NIH also mandates that scientists' copyright agreements with journals and publishers allow articles to be submitted to the PMC database.[44] In adopting this regulation, NIH gave no prior notice, offered no opportunity for public comment, and provided no regulatory analysis. This lack of opportunity for public comment was inconsistent with Congress' direction that "NIH … seek and carefully take into account the advice of journal publishers on the implementation of this policy."[45] As a result, NIH could not – and did not – consider the significant adverse effects of this policy, including its negative effects on international trade and investment in STM publishing.

NIH's Mandatory Public Access Rule revised its prior Voluntary Access Policy, which requested (but did not require) researchers to submit peer-reviewed manuscripts to the PMC database on a voluntary basis.[46] As noted above, while NIH did not engage in an APA notice and comment rulemaking before adopting the Voluntary Access Policy, it did seek comment on that proposal. In responding to such comments, NIH stated that the policy was not subject to either the APA or certain OMB regulatory review requirements because it was voluntary and, therefore, did not "require investigators to do anything other than what the current rules require" and did "not create any new obligations."[47] Indeed, at that time, NIH stated that it lacked the statutory authority "to adopt new regulations" with the force of law.[48]

In the Consolidated Appropriations Act of 2008, Congress instructed the Director of NIH to require that NIH-funded investigators submit peer-reviewed manuscripts to the PMC database within 12 months after the official date of publication.[49] Importantly, however, *Congress also specifically provided that NIH "shall implement the public access policy in a manner consistent with copyright law."*[50] In so doing, Congress plainly recognized that such a mandatory public access requirement would alter existing legal obligations, namely the copyrights to articles arising from NIH-funded research, and substantially impact the STM industry. Indeed, as noted above, the Senate Committee Report accompanying the appropriations legislation "direct[ed] the NIH to seek and carefully take into account the advice of journal publishers on the

---

[43] *See* NIH Mandatory Public Access Rule.

[44] *Id.*

[45] S. Rep. No. 110-107, at 108 (2007).

[46] National Institutes of Health, Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research, NIH Notice Number NOT-OD-05-022 (Feb. 3, 2005) ("NIH Voluntary Access Policy"), *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

[47] *Id.*

[48] *Id.*

[49] Consolidated Appropriations Act 2008, Pub. L. No. 110-161, § 218, 121 Stat. 1844 (2007) (Consolidated Appropriations Act").

[50] *Id.* (emphasis added).

implementation of this policy."[51] Had NIH done so, it would have learned, among other things, that the Mandatory Public Access Rule will threaten revenues of U.S. publishers for journal articles consumed abroad and is likely inconsistent with U.S. international advocacy on copyright and other intellectual property rights. That NIH took no account of these impacts illustrates not only the agency's recalcitrance in complying with existing requirements for regulatory procedures and analysis, but also the need for OMB guidance expressly directing agencies to consider the effects of regulations on international trade and investment.

A. NIH Failed to Comply With the APA in Requiring Mandatory Public Access.

The NIH Mandatory Public Access Rule is a legislative rule subject to the notice and comment requirements set forth in section 553 of the APA. Unlike the Voluntary Access Policy, which according to the agency did not fall within the APA because it imposed no new obligations, requiring researchers to submit peer-reviewed manuscripts to the PMC database and to only enter into copyright agreements that allow such submissions, plainly imposes new obligations on researchers, scientific organizations, journals, and publishers.

NIH seems to suggest that the Mandatory Public Access Rule is simply an interpretative rule or policy guidance, stating that compliance with the policy is a "statutory requirement."[52] But Congress expressly provided in the Consolidated Appropriation Act that "NIH shall implement the public access policy *in a manner consistent with copyright law*."[53] Thus, Congress did not just impose a statutory requirement on researchers: it instructed NIH to consider how that requirement should be implemented. As the AAP has explained to the agency, "[u]nless appropriately implemented, blanket requirements in grant contracts could essentially force authors and publishers to forfeit their copyrights—without compensation for publishers' investments and in conflict with principles of copyright law."[54]

Nor can NIH rely on the exemption in section 553(a)(2) for matters relating to grants. As discussed above, HHS, which oversees NIH, has waived this requirement expressly, directing its subordinate agencies to adhere to the procedures in section 553 of the APA for matters relating to grants. Contrary to the NIH's view, the Mandatory Public Access Rule cannot simply be characterized as a "term and condition of the grant award and cooperative agreement."[55] It does not merely affect the grant recipient. To the contrary, as indicated above, this regulation will have a significant impact – both internationally and domestically – on journals, scientific organizations, and the STM industry as a whole. Not simply a condition incorporated into new grants, the Mandatory Public

[51] S. Rep. No. 110-107, at 108 (2007).

[52] NIH Mandatory Public Access Rule.

[53] Consolidated Appropriations Act § 218 (emphasis added).

[54] Letter from Allan Adler, Vice President, Government & Legal Affairs, Association of American Publishers, to Tevi Troy, Deputy Secretary, Department of Health and Human Services (Jan. 11, 2008).

[55] NIH Mandatory Public Access Rule.

Access Rule stands as an across-the-board mandatory requirement that applies, beginning on April 7, 2008, even retroactively to new articles arising from previously issued grants. Far from a mere funding condition, the Mandatory Public Access Rule imposes new legal obligations, potentially impairing copyright rights, and has wide-reaching consequences, including adverse impacts on the domestic and international economy. The policy should thus be analyzed prior to implementation.

Accordingly, the Mandatory Public Access Rule is a rule that should have been adopted pursuant to the procedural requirements set forth in the APA. Only with full notice and comment proceedings can NIH comply with the legislative command to implement the policy in a manner consistent with copyright law after seeking and carefully taking into account the advice of journal publishers.

B. NIH Failed to Conduct The Regulatory Analysis Required By Executive Order 12866 and OMB Circular A-4.

In adopting the Mandatory Public Access Rule, NIH failed to undertake *any* regulatory analysis whatsoever. Ignoring the rule's substantial domestic and international impacts, the NIH simply issued this new requirement, without any notice, public participation, or analysis. Before mandating free on-line access to publishers' biomedical journal articles, Executive Order 12866 and OMB Circular A-4 required the agency to do much more.

NIH's Mandatory Public Access Rule qualifies as an economically significant regulatory action because it will have an effect on the economy of $100 million or more annually. As noted above, the global market for English-language STM journal articles is $5 billion, and U.S.-based publishers currently command about $3 billion of that market, although that is under substantial competition. Under the Mandatory Public Access Rule, however, publishers' subscription revenues will decline due to the fact that the published articles will be publicly available on line for free. Even a 4% decline in subscription revenue would meet that $100 million benchmark. A 4% decline in subscription revenues due to mandatory free on-line access is conservative, based on a recent survey of librarians.[56] Even with a 12 month embargo period, as adopted by NIH, 44% of surveyed librarians responded they would cancel journal subscriptions if provided free on-line access to journal articles, even where less than half the journal's content would be free on-line within 12 months.[57] Declining subscription levels, moreover, will ultimately affect advertising rate cards for those publications where advertising is a significant revenue stream based on rate base or response.

In addition, many scientific publishers have established fee-based author-paid models of open access. The NIH Mandatory Public Access Rule provides that it will pay reasonable author fees, which are typically $3,000 per article. Using NIH's own estimate

[56] *See* Chris Beckett and Simon Inger, Scholarly Information Strategies Ltd., Self-Archiving and Journal Subscriptions: Co-existence or Competition? An International Survey of Librarians' Preferences (2007) *available at* http://www.publishingresearch.org.uk/documents/Self-archiving_summary2.pdf

[57] *Id*.

of 88,000 articles published annually that reflect research funded in whole or in part by NIH, the Mandatory Public Access Rule would cause at a minimum a reduction of more than $250 million in NIH funds planned for research grants. And that quarter billion in author fees does not include the additional hardware investment and man hours NIH will need to host 88,000 journal articles in the PubMed Central (PMC) database. Those additional costs are estimated by the industry to exceed $200 million. Taking all of these effects together, therefore, the impact of the Mandatory Public Access Rule will no doubt exceed $100 million annually.

Even if the $100 million benchmark were not a part of the standard, the Mandatory Public Access is plainly a "significant regulatory action" because it will "materially alter the budgetary impact of . . . grants . . . or the rights and obligations of recipients thereof." There is no doubt that the new NIH policy imposes considerable changes on the rights and obligations of grant recipients. Previously, researchers, like all authors, had exclusive copyrights in their works that could be transferred or licensed to scientific journals as they saw fit, and journals could, and did, obtain unencumbered rights to peer-reviewed works. Now, however, authors have no choice but to make their peer reviewed manuscripts arising from NIH funds publicly available and all rights to such works are conditioned upon allowing the article to be submitted to the PMC database.

Accordingly, Executive Order 12866 and OMB Circular A-4 required that NIH adhere to the key principles of sound regulatory analysis before implementing the Mandatory Public Access Rule. It was incumbent upon NIH to assess the costs and benefits of its planned implementation, to adopt it only upon a reasoned determination that the benefits of its implementation justify its costs, and to tailor it to impose the least burden on society. This is particularly crucial because, as OMB has recognized, government intervention can do more harm than good and should not be the first option.[58] Indeed, OMB has articulated a presumption against economic regulation in many cases,[59] and urged agencies to carefully review alternatives and to make a reasoned determination that a particular regulation, if any, is needed before intervening in the marketplace.[60] NIH failed to engage in any such analysis when it adopted the Mandatory Public Access Rule, sacrificing transparency, accountability, quality, and coordination in the process. In a plain violation of Executive Order 12866, OMB Circular A-4, and the FY08 appropriations statute itself, NIH has summarily imposed the Mandatory Public Access Rule without any regulatory analysis of its impact on society generally, or on international trade and investment specifically.[61]

---

[58] OMB Circular A-4 at 4, 6.

[59] *See id.* at 6-7.

[60] *Id.* at 7-9.

[61] NIH cannot evade these requirements by attempting to characterize the Mandatory Public Access Rule as a guidance document. As discussed with respect to the APA, this mandatory policy is not simply agency guidance but a binding regulatory action that imposes new, extra-statutory legal requirements with respect to researcher's copyrights. Even if the policy were guidance, however, the recent amendments to Executive Order 12866 would likely require the agency to engage in public notice and comment and a more thorough regulatory analysis.

XII. CONCLUSION

The AAP and the DC Principles generally support the Draft Joint Report's proposal that OMB should provide further guidance to agencies on how to analyze international impacts of proposed legislation. In addition, we specifically urge OMB to ensure that NIH do so before implementing free on-line Internet access, in order to thoroughly analyze impacts on cross-border supply and consumption abroad of U.S. STM journal articles and effectively protect copyright interests in this globalized market.