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COMMITTEE ON
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The Honorable Francis S. Collins, M.D., Ph. D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins:

The Energy and Commerce Committee is engaged in a broad review of agencies under its jurisdiction to prevent federal regulation from undermining the ability of the private sector to create or sustain jobs. The cost of regulation must not exceed any net U.S. public benefit; where it does regulatory relief is essential to a strong economic recovery and boosting job creation. Toward that end, the Committee is examining the impact of the National Institutes of Health (NIH) Public Access Policy and PubMed Central database (PMC) on the science, technology, and medical publishing field.

The NIH Public Access Policy is designed to “accelerate scientific discovery in the biomedical sciences” by providing free access to research results. Under the policy, NIH grant recipients must submit to PMC for posting on-line within twelve (12) months of publication in a scientific journal, any peer-reviewed, publisher-accepted manuscript that reports on the funded research. These prepublication versions are then available worldwide for free on-line.

The science, technology and medical (“STM”) publishing industry is a key player in on-line access to research results. They contract with researchers to publish manuscripts reporting on research. The STM publishing industry expends significant resources to make research articles available on-line. They invest hundreds of millions annually reviewing, selecting and editing manuscripts, managing the peer-review process, and disseminating and archiving articles to ensure the integrity and quality of the research. The academic, research, and professional community, including PMC, depend on the work of the STM publishing community to advance important information on science, technology, and medicine in a format that provides value and facilitates dissemination.

The NIH Public Access Policy appears to undermine the competitiveness of the STM publishing industry. While NIH funds the research, it does not fund the publishing. The Public Access Policy limits the STM publishing industry to 12 months to recoup their considerable costs of validating and publishing the article before NIH offers it for free. Without an ample amount of time to market the publications, the STM publishing industry cannot offset their costs. For example, the American Psychological Association (APA) that publishes 56 scholarly journals

tracks their download usage. Their data show that the vast majority of downloads occur well after the first year when the Public Access Policy makes their articles freely available, negatively impacting their business. In addition, there are concerns that PMC is undermining American competitiveness by enabling free foreign access to the product of U.S. research and exposing U.S. journal articles to foreign piracy. We understand that approximately two-thirds of PMC usage is from outside the U.S.

NIH has asserted that the public needs free access and that publishers are not being harmed by its policy. They have also stated that "large academic institutions and drug/device companies lack access" to journals. Yet, the STM publishing industry offers initiatives that make authoritative articles available to patients, their families, and the public at no or low cost.

In order to assist the Committee's work on the impact of the Public Access Policy and PMC on the science, technology, and medical publishing field, we request that you respond to the following questions:

1. NIH has asserted in congressional testimony that PMC is "accelerating scientific discovery in the biomedical sciences." What evidence does NIH have to support this claim? Does NIH have any data on the benefits derived from manuscripts deposited under the mandatory Public Access Policy, such as research productivity by scientists who otherwise would not have had access to publishers' contents?
2. NIH has stated that "large academic institutions and drug and device companies can lack access" to journals. Do you have market survey data that shows who amongst these institutions are not getting access and to what they are not getting access?
3. Concerns have been raised that PMC is undermining American competitiveness by enabling free access to the product of U.S. research and exposing U.S. journal articles to foreign piracy. Has NIH taken steps to protect publishers' from their revenue being eroded by piracy? What steps has NIH taken to ensure that publishers' interests are respected by NIH staff and PMC users? Has NIH recently analyzed usage by non-U.S. citizens and organizations, which, by NIH's earlier report, accounts for two-thirds of total usage?
4. Questions have been raised about NIH's cost estimates to operate PMC – including staff time on PMC and on travel coordinating international mirror sites, related infrastructure spending, acquisition and input of articles and inter- or intra-agency contracts and transfers such as payments from NIH Institutes or Centers to National Library of Medicine (NLM) and National Center for Biotechnology Information (NCBI). What are these costs and what proportion of these costs are for articles that fall under the NIH Public Access Policy?
5. Although publishers do not pay peer reviewers, they add value to manuscripts through the significant cost of organizing and managing reviewers, and financial

- support of the peer review process. For those grants for which NIH does cover peer-review, what is the full aggregate cost for NIH, on an annual basis? Your predecessor has testified that the annual cost is \$80-\$100 million. Are these costs deducted directly from grant funds, or do they come from other operating lines?
6. NIH has asserted that "the success of the NIH model has stimulated similar efforts in other countries." Yet, the efforts of these other funding bodies are quite different. Funding agencies such as the Wellcome Trust and Medical Research Council in the UK have developed arrangements for publishers to recoup their investment by paying a fee to sponsor access to articles while other funders instruct authors to comply with publisher policies. Is the NIH considering adopting similar mechanisms and how does the NIH justify its approach in contrast to these other approaches that fund open access and do not threaten jobs in STM publishing?
7. NIH has asserted that "[w]ithout a resource like PubMed Central, the general public does not have ready access to much of the biomedical literature[.]' Why does NIH not take into consideration its own public communications efforts (e.g., through individual institute web sites), as well as publisher initiatives that make articles available to patients, their families, and the public at no or low cost; or consider working with publishers and patient organizations to support programs such as PatientINFORM that make articles and interpretive material specially created for a lay audience available to the American public?

Please respond to these questions within two weeks of the date of this letter and arrange for a briefing with Committee staff at the earliest point thereafter. If you have any questions, please contact Brenda Destro with the Committee staff at (202) 225-2927.

Sincerely,



Joseph R. Pitts
Chairman, Subcommittee on Health

cc: The Honorable Fred Upton, Chairman
The Honorable Henry A. Waxman, Ranking Member
The Honorable Frank Pallone, Jr., Ranking Member
Subcommittee on Health