

**CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA**

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October 22, 2004

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

Re: Comments Regarding Notice of Enhanced Public Access to NIH Research
Information

Dear Dr. Zerhouni:

The U.S. Chamber of Commerce (Chamber), the world's largest business federation, representing more than three million businesses of every size, sector, and region, is pleased to provide the following comments concerning the National Institutes of Health's (NIH) proposed action: "Enhanced Public Access to NIH Research Information."¹

The Chamber's comments emphasize three main issues that are discussed in more detail below. These key points are that the Chamber:

- supports NIH's initiative to establish open access to scientific information that is produced at taxpayer expense;
- opposes a six month delay in the open access publication of such information, preferring instead that such information be made available immediately; and
- contends that all taxpayer funded models, model source codes, and data used in support of published information should also be made available through open access to the public.

SUPPORT FOR OPEN ACCESS

The Chamber strongly supports NIH's effort to ensure that scientific information arising from NIH-funded research is made freely available, in a timely manner, to other scientists, health care providers, students, and teachers, as well as to the millions of other stakeholders searching the Web to obtain credible health-related information. Taxpayers should not have to pay for access to information that has already been paid for through the

¹ NIH, Notice: Enhanced Public Access to NIH Research Information, Notice Number NOT-OD-04-064, Release Date, September 3, 2004; <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-064.html>.

expenditure of public funds and that is required by law to be publicly available.² Moreover, the free and timely dissemination of scientific knowledge produced by NIH-funded research to all stakeholders will advance the pace of scientific progress and facilitate the public's and industry's ability to become better informed of the current state of scientific knowledge.

The Chamber applauds NIH's intent to request that grantees and supported principal investigators provide it with electronic copies of all final version manuscripts³ in instances where the research was supported in whole or in part by NIH funding, inclusive of all research grants, cooperative agreements, and contracts, as well as National Research Service Award fellowships.

NEED FOR MORE COMPREHENSIVE ACCESS

NIH should further provide free and timely public access to all annual and final progress reports in instances where such material is produced in whole or in part with taxpayer funds. Such an additional requirement is consistent with the intent of the Shelby amendment,⁴ which aims to ensure that all taxpayer-supported research is put into the public domain in a timely manner.

NIH should also provide free and timely public access to all⁵ supplemental materials that support scientific work paid for in whole or in part with public funds; including all models and data used in support of taxpayer-funded research and scientific findings. If the public cannot access this information it will be difficult for stakeholders to establish the scientific soundness of research findings. Without this unfettered public access, such findings cannot be tested and verified as to their reliability.

In no instance should models and their source codes that were developed in whole or in part through the expenditure of public funds be treated as proprietary, with public access denied. Except for the implementation of reasonable precautions to assure that the specific identities of individual patients and test subjects are not disclosed, the Chamber contends that there is no valid reason why all data used to produce taxpayer-funded scientific findings, particularly those that are used in formulating regulatory policy, cannot be made publicly available in a timely manner. Moreover, making all such data and models available is consistent with, and continues in spirit, the intent of the Shelby amendment to assure ready public access to such taxpayer-funded information.⁶

² "Provided further that the director of OMB amends Section __.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public..." 112 Stat. 2681-495 Public Law 105-277-Oct. 21, 1998.

³ A final manuscript is the author's version resulting after all modifications necessitated through peer review.

⁴ Footnote 2, *Ibid.*

⁵ There is one reasonable exception: the privacy of individuals should be protected by preventing the release of information that would specifically disclose their identities.

⁶ Footnote 2, *Ibid.*

PUBLIC ACCESS TO GOVERNMENT-FUNDED DATA MUST BE A PRIORITY

NIH considers final manuscripts to be an important record of the research that is funded by the government and states that it will archive these manuscripts and any appropriate supplementary information⁷ in PubMed Central (PMC), NIH's digital repository for biomedical research. According to NIH, six months after the publication of an NIH-supported research study, such manuscripts will be made available freely to the public through PMC—or sooner if the publisher agrees.

The Chamber strongly disagrees with the proposed six-month delay for publishing taxpayer-funded information. Marc Kirschner, professor of systems biology at Harvard Medical School, comments⁸ that: “the six-month publication delay is inappropriate because it prevents scientists from immediately [emphasis added] accessing research critical to their own work.” And Nobel Prize winner Harold Varmus, chairman, Public Library of Science, and president, Memorial Sloan-Kettering Cancer Center, has observed:

The [proposed NIH] policy is admirable and a step in the right direction, but it's not open access. The ultimate goal is true open access, with publications available at the time they are issued [emphasis added].⁹

As recently noted by 25 Nobel Prize winners:

Science is the measure of the human race's progress. As scientists and taxpayers too, we therefore object to barriers that hinder, delay or block the spread of scientific knowledge supported by federal tax dollars including our own works.¹⁰

The Chamber also notes the recent draft House Appropriations Committee directive, which states:

The Committee is very concerned that there is insufficient public access to reports and data resulting from NIH-funded research. This situation, which has been exacerbated by the dramatic rise in scientific journal

⁷ This should be inclusive of all models and data used in support of such published scientific findings.

⁸ Harold Varmus as cited in Paula Park, “NIH Unveils Open Access Draft” *The Scientist*, September 8, 2004; <http://www.biomedcentral.com/news/20040908/04>.

⁹ *Ibid.*

¹⁰ Agre, P. et al. *An Open Letter to the U.S. Congress*, August 26, 2004. [Press Contact: Dr. Richard J. Roberts (Nobel Prize in Physiology or Medicine, 1993), e-mail Roberts@neb.com].

subscription prices, is contrary to the best interests of the U.S. taxpayers who paid for this research.¹¹

The Chamber fully concurs with the sentiments expressed in the above observations and contends that the free and timely dissemination of scientific knowledge produced by NIH to all stakeholders is essential for advancing the pace of scientific progress. With ready access to such taxpayer-funded information, stakeholders are better informed and able to engage in constructive, informed public dialogue with others, resolve uncertainties, and, relevant to business interests, the Chamber's members are better able to plan future business operations. This outcome is good for America and good for American industry, as it will create new business opportunities, thereby strengthening our economy and making America more competitive in the global marketplace.

In sum, the Chamber strongly encourages NIH to assure that all taxpayer-funded published information, inclusive of final publications, progress and final reports, models and their source codes, and data be freely disseminated to the public, immediately if possible, and if not that, then as soon as is practical thereafter.

Sincerely,

William L. Kovacs

¹¹ U.S. House of Representatives Committee on Appropriations Draft Companion Report 108-xxx [Full Committee Print] to the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 2005, (undated draft), pp. 102–103.