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August 25, 2004

Dr. Elias Zerhouni
Director, National Institutes of Health
Building 1
Bethesda, MD 20892

Re: August 31, 2004 Meeting – NIH Policy, Improving Access to Biomedical Research Results

Dear Dr. Zerhouni:

Thank you for the invitation to meet with you and public interest organizations as NIH considers ways to improve access to biomedical research results, especially in light of recent proposals for NIH to provide “open access” or copies of papers published in scientific journals. Our organization – the AIDS Vaccine Advocacy Coalition (AVAC) – joined six other groups to provide initial comments on this topic in our letter to you dated August 6, 2004. We regret not being able to attend the scheduled August 31 meeting, only because it coincides with a previously scheduled significant international AIDS vaccine conference that all our staff must attend. That conference is essential to our primary organization program. Otherwise we would take you up on the kind offer to discuss access to research issues.

In lieu of our attendance, please consider these additional bulleted/written remarks while NIH develops a revised publications policy. We understand NIH may soon seek formal public comment either in the Federal Register or, perhaps, through revisions to its NIH Grants Policy Statement (http://grants2.nih.gov/grants/policy/nihgps_2003/). In either case, these suggestions may be useful ideas for that effort:

- NIH could consider both immediate, short term and long term solutions to widen the public’s access to research publication based on government funded work. AVAC and other groups support the immediate Appropriations Committee proposal to develop an NIH policy using PubMed Central but our goals need not be limited to that first step mechanism;
- Published work made possible with funds provided in whole or in part by the public is not limited to study results from full clinical trials; it may also include work involving preclinical or laboratory investigations that lead to clinical trials with human subject participation and also opinions, reviews and overall evaluations by government (NIH) scientists.
- NIH could expand open access policy even without new authorization or direction from Congress by revising its Grants Policy Statement. That guideline already states: “It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PIs and grantee organizations are

expected to make the results and accomplishments of their activities available to the research community and to the public at large.... 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 authorize others to do so for Federal purposes.”

http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm Expansion of the policy at this time to promote open access is warranted.

- Practical models to increase open access to research are not mutually exclusive or incompatible with the requirements of traditional publishers and may include: a) a stated NIH preference in grant application scoring that its grantees publish in good peer reviewed journals that promote open access, b) subsidies to allow traditional or alternative journals to offer open access for articles; c) peer review support and encouragement for reliable open access journals so that they would naturally increase their reputation, authority and desirability as publishing venues for a variety of noted scientists. We look forward to presenting ideas more formally when NIH seeks other comment.

The short scheduling time frame prevents us from being able to meet with you personally on August 31, and we hope we get another opportunity to do that. Please call either of us, Mitchell Warren (212/367-1084) or Robert Reinhard (415/268-7469), if you have any questions, or by email: Mitchell@avac.org or rreinhar@mofa.com . AVAC is described on the web at <http://www.avac.org>.

Sincerely,



Mitchell Warren
Executive Director, AVAC



Robert Reinhard
Board Member, AVAC

CC: Anita Linde, NIH
Karen Rudolph, NIH