Office of the President

March 16, 1999

The Honorable Jacob Lew
Director, Office of Management
and Budget
Washington, D.C. 20503

Dear Mr. Lew:

I am writing with respect to the language included in the Omnibus Appropriations Act (Public Law 105-277) that directs the Office of Management and Budget to revise Circular A-110. This legislation would require federal agencies, including those involved in funding of biomedical research to ensure that all data produced under an award from the federal government would be made available to the public through the procedures under the Freedom of Information Act (FOIA).

I am President of the Memorial Sloan-Kettering Cancer Center, the largest, freestanding comprehensive cancer center devoted to research, patient care and education related to cancer in the United States, a former member of a number of advisory committees to the National Institutes of Health, including the President's Cancer Panel and Co-Chairman of the Advisory Committee to the Director, NIH, which reviewed the Institutes' programs, and a recipient of federal funding for support of research.

The statute's language, broadly interpreted, would have disastrous and unintended consequences for this country's biomedical research program, including clinical trials for new diagnostic, therapeutic, or preventive measures.

The statute's language states that it applies to "all data" developed by recipients of funding from federal agencies, which would include the NIH and the NCI. The requirement for such disclosure under the FOIA could be in direct conflict with commitments to patients' privacy and confidentiality agreements, such as those common in academic-industrial collaborations.

Further, "all data" could include data of a very preliminary nature which have not been tested for validity through the traditional scientific research processes, such as verifications of data by repetition of studies or peer-review of reports submitted for publication. Such disclosure of data could undermine the multiple efforts on the part of investigators to assure the quality of the research product and, therefore, run the risk of disclosure which is possibly incomplete, misleading and even incorrect.

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The statute does not make clear what would represent federally supported research. In today's environment, funds from federal sources frequently represent only a portion of the total support of a research effort. Other sources may include institutional and corporate funding where specific agreements have been reached with regard to the procedures for disclosure of the information. The statute could lead to a conflict with the current policies of the National Institutes of Health which encourage federally funded investigators, under appropriate conditions, to seek industrial partners for the necessary and desirable exploitation of research findings for the public good.

The potential that any data developed by recipients of federal funding to support research could be subject to disclosure under the FOIA would also run the risk of discouraging investigators to seek federal funding, discourage individuals from participating in clinical trials, and discourage industry from seeking collaborations with investigators receiving federal funding.

In addition to the above outline of potential major constraints as a consequence of this statute to the pursuit of the best possible research, there is the time and cost burden of providing the information.

I would emphasize that I fully recognize the responsibility of recipients of federal funding to disclose research findings in a timely and complete fashion. As someone who has been in a position of leadership of institutions that have been major recipients of federal funding (Columbia University College of *Physicians & Surgeons*: Vice President and Dean for Health Sciences, 1970-1980; and President of Memorial Sloan-Kettering Cancer Center, 1980-present), I have been committed to fully meet these responsibilities on an institutional level and on the level of the individual members of our staff. For the reasons outlined above, I strongly urge revision of the revisions to the OMB Circular A-110 ordered by Public Health Law 105-277.

Respectfully submitted,

Paul A. Marks, M.D.

PAM/mw