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To: "'OMB\_peer\_review@omb.eop.gov'" <OMB\_peer\_review@omb.eop.gov>

cc: "Stanley Schrier MD (E-mail)" <sschrier@stanford.edu>, Martha Liggett

<mliggett@hematology.org>, Mila Becker <MBecker@hematology.org>, Jeffrey Coughlin

<Jcoughlin@hematology.org>

Subject: American Society of Hematology Comment Letter on Peer Review

May 13, 2004

Dr. Margo Schwab

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May 13, 2004

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
725 17<sup>th</sup> Street, NW
New Executive Office Building
Room 10201
Washington, DC 20503

Dear Dr. Schwab,

On behalf of the American Society of Hematology (ASH), I am writing to comment on the Revised Information Quality Bulletin for Peer Review. ASH represents nearly 10,000 U.S. members that contribute extensively to and rely heavily upon research findings, data, and other information that may be incorporated in disseminations by the Public Health Service (PHS).

ASH had serious objections to OMB's first bulletin, proposed in September 2003, and believed it was inappropriately restrictive and could potentially interfere with timely decision making by the Public Health Service. The revised bulletin considerably improves upon the earlier version, and provides far more flexibility and deference to scientific and public health prerogatives of government agencies.

While the Society continues to question the justification for why new government-wide peer review standards are needed, the revised bulletin is a step in the right direction. For example, the original version would have established criteria for peer selection that would have precluded the use of agency grantees in an OMB-mandated peer review, under the presumption that receipt of a research grant could constitute a conflict of interest in critiquing a funding agency's dissemination of information. ASH and others commenting on the proposed bulletin believed that this would have biased the new review process toward favoring industry. ASH is pleased that the revised bulletin does not consider agency grantees to hold such conflicts. The revised bulletin also recognizes scientific expertise as the chief criterion for a reviewer's qualifications, and holds up the National "Academies' procedures and standards as a model for achieving balanced, expert, and independent review of federal actions. Further, the revised bulletin addressed a major concern of ASH by providing various exemptions from the added peer review requirement, such as in the case of urgent findings from a clinical trial, where the trial itself has already been peer reviewed.

ASH appreciates the close attention that OMB afforded the research community's comments in its formulation of the revised bulletin and is grateful for the consideration of

its comments by OMB's Office of Information and Regulatory Affairs. The Society would be pleased to engage in further discussions about our concerns and possible remediation.

Sincerely,

Stanley L. Schrier, MD

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President