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July 26, 2011

Honorable Kathleen Sebelius  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

John P. Holdren  
Director  
Office of Science and Technology Policy  
Executive Office of the President  
725 17th Street, Room 5228  
Washington, DC 20502

**RE: Advance Notice of Proposed Rulemaking (ANPRM) — Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators (Docket number HHS-OPHS-2011-0005)**

Dear Secretary Sebelius and Dr. Holdren:

Public Citizen's Health Research Group (HRG) has the following preliminary comment regarding the above-referenced ANPRM:

Given the length and complexity of the ANPRM, a 60-day comment period for responding to this notice is grossly inadequate. The ANPRM proposes sweeping changes to long-standing federal regulations for the protection of human research subjects and poses 75 detailed questions, most of which have multiple sub-questions. The short comment period — combined with the timing of publication in late summer, when key staff members at many stakeholder organizations typically have scheduled vacations — suggests that the Department of Health and Human Services (HHS) is not sincerely interested in obtaining substantive and meaningful comment on these proposals.

Revising the federal regulations for the protection of human subjects is an important undertaking but not an emergency. Accordingly, the departments and agencies that promulgated the Federal Policy for the Protection of Human Subjects should proceed only after a careful, deliberative process that allows sufficient opportunity for members of the public to comment. A comment period of at least 120 days would enable interested members of the public to carefully consider the proposals outlined in the

ANPRM and thoughtfully respond to the many important and complex questions posed. Therefore, we call upon HHS to promptly issue an amended ANPRM that extends the comment period to a minimum of 120 days.

On a related topic, we are aware that last week HHS convened a conference call with key stakeholders who may have an interest in the ANPRM. HRG, which has a long-standing interest in the protection of human subjects, was not invited to participate in this call. Please include HRG when inviting stakeholders to participate in any such calls in the future.

I look forward to a timely response to our request to extend the comment period for the ANPRM.

Sincerely,

A handwritten signature in blue ink, appearing to read 'S. Wolfe', with a stylized flourish at the end.

Sidney M. Wolfe, M.D.  
Director  
Public Citizen's Health Research Group

cc: Dr. Jerry Menikoff, Director, Office for Human Research Protections