March 9, 2016

The Honorable Karen B. DeSalvo
Acting Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Jerry Menikoff, M.D., J.D.
Director
Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

RE: Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) Trial and Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) Trial

Dear Dr. DeSalvo and Dr. Menikoff:

We have been following with great concern the recent disclosures by Public Citizen and the American Medical Student Association (AMSA) of serious ethical and regulatory lapses identified in the design, review, and conduct of the iCOMPARE and FIRST trial that are presented in their letters to the Office for Human Research Protections (OHRP) on November 19, 2015; February 11, 2016; and today.

Particularly troubling are the determinations by some institutional officials that these trials did not involve human subjects research, as defined by the Department of Health and Human Services regulations for the protection of human subjects; the failures to ensure that risks to subjects were minimized by using procedures that are consistent with sound research design; and the failures to obtain the voluntary informed consent of the subjects enrolled in the trials.

The lapses identified by Public Citizen and AMSA are serious, substantive, and supported by extensive documentation that has been provided to OHRP. We strongly support Public Citizen an AMSA's calls for OHRP to immediately launch formal compliance oversight investigations into both trials. If OHRP fails to investigate and correct the serious mistakes made in the review and conduct of both trials, then the agency effectively is giving a green light for other researchers and institutional review boards to just come up with other exceptions to the human subject protections regulations, no matter how implausible and no matter the dangers posed to human subjects.

Thank you for your prompt attention to this urgent matter.

Sincerely,

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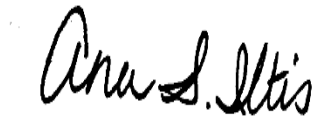

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