



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

April 4, 2014

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Dear Dr. Carome:

Thank you for your letter regarding The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants: The SUPPORT Trial.

The purpose of the August 28, 2013, meeting held by the Department of Health and Human Services (HHS), which you attended, was to seek public input and comment on how certain provisions of the federal policy for the protection of human subjects should be applied to research studying one or more interventions which are used as standard of care treatment in the non-research context.

In addition, as was noted in the Office for Human Research Protection's (OHRP) June 4, 2013, letter to the University of Alabama at Birmingham (UAB), HHS has put on hold all compliance actions against UAB relating to the SUPPORT case and plans to take no further action in studies involving similar designs until the process of producing appropriate guidance is completed. HHS is actively working on the guidance.

We appreciate your concerns about the protection of human research subjects. Please contact Kristina C. Borrer, Ph.D. of the Office for Human Research Protections at (240) 453-8132 if you have further questions. I will also provide this response to the co-signer of your letter.

Sincerely,

A handwritten signature in black ink, reading "Kathleen Sebelius". The signature is written in a cursive style with a large initial "K".

Kathleen Sebelius