



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

July 23, 2013

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

Dear Dr. Carome:

Thank you for your letters about the *Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT)*. I appreciate your interest in the protection of human subjects.

Please note that the Office for Human Research Protections (OHRP) evaluation you reference in your letters related to the study is still ongoing, and therefore we cannot comment on the issues you raise regarding the particulars of this research or OHRP's evaluation. We will seriously consider your broader recommendations regarding the Department of Health and Human Services system for the review and oversight of research involving human subjects.

The Department will host a public meeting on August 28, 2013 to seek public comment and input on issues related to the protection of human subjects; more information on the meeting is available at: <http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2013-0004-0001>. I encourage you to participate and share your written comments through this process.

You may contact Dr. Kristina Borrer at (240) 453-8132 if you have any further questions or concerns. Thank you again for your interest in this matter. I will also provide a similar response to Dr. Sidney Wolfe, who cosigned your letters.

Sincerely,

A handwritten signature in cursive script that reads "Kathleen Sebelius".

Kathleen Sebelius