

2413 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-0703
(202) 225-3661

59 ELM STREET
SECOND FLOOR
NEW HAVEN, CT 06510
(203) 562-3718

DURHAM/MIDDLEFIELD/MIDDLETOWN
(860) 344-1159

WEBSITE: [HTTP://DELAURO.HOUSE.GOV](http://deLauro.house.gov)



UNITED STATES
HOUSE OF REPRESENTATIVES

ROSA L. DELAURO
3RD DISTRICT, CONNECTICUT

CO-CHAIR, DEMOCRATIC STEERING AND
POLICY COMMITTEE

COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEES
RANKING MEMBER

LABOR, HEALTH AND HUMAN SERVICES,
EDUCATION, AND RELATED AGENCIES
AGRICULTURE, RURAL DEVELOPMENT,
FOOD AND DRUG ADMINISTRATION,
AND RELATED AGENCIES

May 20, 2014

The Honorable Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Inspector General Levinson:

I am writing to express my serious concern about a potentially inappropriate Health and Human Services (HHS) interference with the Office for Human Research Protections' (OHRP's) investigation of the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (the SUPPORT study). Public Citizen has revealed very disturbing new information regarding the conduct of the National Institutes of Health (NIH) funded study and the subsequent OHRP investigation.

I understand you were sent a letter from Public Citizen, as well as several bioethicists and academic scholars that describes in detail a series of email communications from April-June 2013 among officials at NIH, the HHS Office of the Secretary, and OHRP that document how NIH, despite having obvious substantial conflicts of interest, was allowed to interfere and improperly influence OHRP's investigation of the SUPPORT study. Most troubling, it appears that numerous officials at the very highest levels of HHS were aware of this interference, which unfolded after OHRP determined that the consent forms for the SUPPORT study failed to adequately inform parents of infants enrolled in the study of the reasonably foreseeable risks of the research.

As I am sure you are aware, the very reason OHRP was administratively moved out of NIH was because of the long-recognized conflicts of interest that exist between NIH and OHRP. That move was intended to prevent exactly the type of NIH interference that has now apparently occurred during OHRP's investigation of the SUPPORT study. It appears the actions displayed by senior HHS leaders in allowing NIH's interference in this matter have compromised the integrity and independence of OHRP's ongoing investigation into the SUPPORT study.

I support the request from Public Citizen that your office immediately launch a formal investigation of this matter in order to ensure that all HHS officials who played a role in it are held accountable and that appropriate corrective actions are taken to prevent such improper and unethical interference by NIH from recurring. I further encourage your office to assess

whether OHRP needs to be relocated, and if so where, in order to prevent the type of NIH and other HHS interference that seem to have occurred in this episode.

Thank you for your prompt attention to this urgent matter. I look forward to your confirmation that your office will be thoroughly investigating this matter.

Sincerely,

A handwritten signature in blue ink that reads "Rosa L. DeLauro". The signature is written in a cursive, flowing style.

ROSA L. DeLAURO
Member of Congress