



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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September 2, 2010

Mary Simmerling, Ph.D.
Director, Responsible Conduct of Research
Weill Cornell Medical College
445 E. 69th Street
Olin 210
New York, NY 10021

Jeff Silverstein, MD
Associate Dean for Research
Mount Sinai School of Medicine
1 Gustave L Levy Place Box 1075
New York, NY 10029

RE: Research Project: Steroid 21-Hydroxylase Deficiency
Research Project: Hypo- and Hyperadrenal States
Research Project: Low Renin Hypertension
Research Project: Long Term Outcome in Offspring and Mothers of Dexamethasone-Treated Pregnancies at Risk for Classical Congenital Adrenal Hyperplasia Owing to 21-Hydroxylase Deficiency

Principal Investigator: Maria New, M.D.

Dear Drs. Simmerling and Silverstein:

This letter is in response to your reports to the Office for Human Research Protections (OHRP) regarding use of dexamethasone in pregnant women at risk of carrying a female fetus with congenital adrenal hyperplasia (CAH). OHRP has received your most recent letters of July 29, 2010 and August 2, 2010, concerning the above protocols. This correspondence relates to allegations OHRP received concerning activities conducted by Dr. Maria New at Weill Cornell Medical College (WCMC) and Mount Sinai School of Medicine (MSSM). Your reports and the actions described appear to be appropriate under HHS regulations and your institutions' Assurances of Compliance.

As you know, in evaluating this matter, OHRP first received reports from your institutions. We then sent you each several requests for additional information, which we reviewed thoroughly, including the research protocols and informed consent documents, and publications resulting from the research. We also had numerous discussions with staff at the U.S. Food and Drug Administration (FDA). As a result of

our review, we determine that the allegations raised by the complainants are unproven and we find no evidence that Dr. New violated the Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced research.

In specific, OHRP notes the following:

- (1) Dr. New conducted 3 studies while employed at WCMC involving provision of dexamethasone to pregnant women at risk of carrying a female fetus with CAH. The studies were reviewed and approved by the WCMC Institutional Review Board (IRB). Written informed consent (which included disclosure of risks) was obtained from subjects for participation in these studies. We find nothing inappropriate in either the IRB approval or conduct of these studies. From the information we reviewed, there appears to be no evidence that Dr. New engaged in clinical use of dexamethasone outside of research while at WCMC.
- (2) Since her arrival at MSSM in 2004, Dr. New has conducted one study that enrolled human subjects related to the use of dexamethasone in pregnant women at risk of carrying a female fetus with CAH. This project, which was initially reviewed by a MSSM IRB in 2004, involved cognitive testing and outcomes follow-up of patients who either had or had not been treated with dexamethasone during the prenatal period. According to the protocol, the decision as to whether a pregnant woman was treated or was not treated was not part of the study. We find nothing justifying a conclusion that the actions of the clinicians in treating those women should have been considered part of a clinical trial and subjected to IRB review. Dr. New was not the physician at MSSM for any of the cases included in her study. During Dr. New's tenure at MSSM, she prescribed dexamethasone for only one pregnant woman who had already been diagnosed with CAH. In this case, the treatment was not designed to prevent ambiguous genitalia in the fetus, but to continue needed treatment for the CAH-affected mother.

We are attaching a memo from the FDA summarizing their evaluation of the matter.

OHRP appreciates your continued commitment to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borrer, Ph.D.
Director, Division of Compliance Oversight