Congress of the United States
Washington, DC 20515

January 24, 2012

The Honorable Kathleen Sebelius
Secretary
U. S. Department of Health and Human Services
200 Independence Avenue, S. W.
Washington, D. C. 20202

Dear Secretary Sebelius,

As the Department revises the "Common Rule" regulations on human participation in research, we would like to express our concern at the lack of attention to improving guidance on research with pregnant women.

It is critical that we understand how to safely and effectively treat pregnant women, including the 500,000 women who face serious medical illness while pregnant each year in the United States. In addition to those women, the CDC has estimated that approximately 133 million Americans suffer from chronic illnesses, many of which may require medical management. This includes approximately 12.6 million women – 10.8% of all women over the age of 20 – with diabetes. Without carefully designed and implemented clinical research into the needs of pregnant women, these women and their doctors weigh their treatment options without basic information about the likely impacts of those treatments.

Unfortunately, as you know, there is a scarcity of research on the impacts of drugs and other treatments on pregnant women and their fetuses. Researchers have avoided the issue and are often deterred by the vague and overly broad nature of current regulatory language. Until regulations provide better guidance on the parameters of responsible research with pregnant women, women may continue to compromise their health with treatment based on guesswork rather than evidence.

We urge you to ensure that the regulations being developed follow the lead taken in pediatric research and be fashioned in a way that balances the need for strong patient protections with best practices for gaining an evidence base for proper treatment. The goal of these regulations should be to provide adequate protection for pregnant women while developing scientifically-based information regarding the safety and efficacy of medications and treatments in pregnant women. It is imperative that these regulations encourage the gathering of this critical information in safe and appropriate ways.

Thank you for your attention to this public health issue.

Sincerely,