Title: FDA Office of Women’s Health Funded Biological Studies: 1994-2009, a summary report

Purpose:
Sex-based biology is a growing area of research that shows clinical benefits for both men and women. The exclusion of women from some past clinical studies has resulted in knowledge gaps about the effects of medical treatments on women. FDA Office of Women’s Health (OWH) has supported sex-based biological studies since 1994. Completed studies were reviewed for their regulatory and public health impact.

Methods:
Completed OWH-funded studies with the Center of Biologics Evaluation and Research (CBER) were classified into broad disease area categories: Sex hormones effects, HIV/AIDS, and Diseases Common in Women. They were assessed for their public health or regulatory impact.

Results:
Among the 27 biologics-related studies, 17 were completed. The findings are grouped into three categories:

Sex hormones effects:
- Hormonal differences in response to CpG ODN (oligodeoxynucleotides) as assessed by cytokine secretion.
- β-estradiol and progesterone inhibit the efficacy D4T (Stavudine) in PBMC cultures
- Estrogen intensifies the inhibition of HCV growth in the presence of alpha interferon
- Hormone state is a potential factor in gonococcus infection
- Sex may affect the susceptibility of thymic gland to steroid treatment
- Increased 17β-estradiol and reduced Dehydroepiandrosterone sulfate (DHEAS) levels in lupus patients may induce cytokine abnormalities early in the disease. However, subsequent cytokine imbalance does not correlate with sex hormone levels.

HIV/AIDS:
- A novel HIV Diagnostic test has been developed to differentiate between antibody responses due to vaccination versus actual HIV infection. The sensitivity of the test showed no significant difference in men and women.
- Viral subtype and sex hormones may play a role in the transmission of HIV
- Intranasal immunization may protect individuals from HIV-1 infection

Diseases Common in Women:
- Most systemic lupus erythematosus and rheumatoid arthritis patients are unable to assemble complete transcription complexes in response to INFα, resulting in impaired INFα signaling.

Conclusion:
OWH has supported biological studies that have regulatory impact and advance the understanding of sex differences in disease diagnosis and treatment. Further development and licensure of HIV test is currently underway. The results of OWH funded biological research have yielded 26 publications in peer-review journals.