

**New Jersey State Commission on Cancer Research
LAY ABSTRACT OF RESEARCH PROJECT**

NAME OF PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR: **Grace Lu-Yao**

Project Title: **Testosterone Supplementation and Risk of Prostate Cancer**

Description: **The proposed study will examine the association between the risk of dying from prostate cancer and the use of male hormone supplementation.**

Testosterone (T) supplementation, whether in the form of prescribed steroids or over-the-counter athletic or nutritional supplements, has become increasingly popular. There were over 2 million T prescriptions in the US alone in 2002 and from 2000 to 2004, T utilization increased by nearly 300%. Despite this, there has been growing concern about the lack of data concerning the associated benefits and risks. Due to limited data, information on the long-term impact of T supplementation has been confined to studies that involved only ~100 patients followed over 3 years. The proposed study is designed to help fill critical knowledge gaps identified by the Institute of Medicine and others regarding the use of T supplementation and risk of prostate cancer. In particular, this study will examine whether T supplementation is associated with increased prostate cancer mortality.

The proposed study will include about 320,000 subjects with over 13 years of follow-up in order to determine the risk of prostate cancer associated with T use. Cancer registry data from the Surveillance, Epidemiology, and End Results (SEER) program and linked Medicare data will be used for the proposed study. Standard statistical methods will be used to determine the time from first T use to the development of prostate cancer or prostate cancer death. Modern statistical methods designed to minimize biases will be employed. The large sample size in the proposed study (in comparison to previous studies) will have the potential to more accurately determine if T supplementation is associated with a clinically significant increase in the risk of prostate cancer and prostate cancer death. Because of the increasingly widespread use of T, as well as nutritional and athletic supplements with activity mediated through the T pathway, the information from the proposed study may have important public health implications for prostate cancer, its causes and potential for prevention. The lifetime risk of prostate cancer is one in six among American men. About 8,000 men are diagnosed with prostate cancer annually in New Jersey. If T supplementation can modify the risk of prostate cancer, the insight gained from this study will be a valuable tool to prevent prostate cancer.