

## Dr. Gary Donovitz Responds to PLOS One Study

The recent report that testosterone supplements are linked to increased risk of heart attack risk in men in PLOS One is both misleading and inaccurate. As the Medical Director of the largest and most comprehensive hormone replacement company in the United States, **BioTE Medical**, I find this study flawed in design and harmful to the public who will be misled by its conclusions.

The study looked at 55,593 men retrospectively. The study was limited to men using testosterone gel and creams and some synthetic testosterone injections. It did not consider data for men receiving **subcutaneous bio-identical testosterone pellet therapy**. Furthermore, there was no lab data pre or post therapy.

Numerous studies have shown that **natural testosterone pellet therapy** can reduce the risk of heart disease, type 2 diabetes mellitus, Alzheimer's disease, osteoporosis, and prostate cancer. A key component of this treatment is an accurate interpretation of a patient's laboratory values. In the PLOS One study, this data was not considered. Bio-identical testosterone pellet therapy also includes the optimization of each patient's hormone levels to achieve a level that is above a discriminatory zone that reduces heart disease and the other diseases noted above. Dosage optimization is not possible with creams and gels.

It is troubling that the authors cite the Veterans Administration Study reported in The Journal of the American Medical Association (JAMA 2013), because their conclusions completely misstate their own data. Cardiovascular events occurred in 21% of males not taking testosterone and 10% of those males on testosterone. In addition, the males with testosterone levels in excess of 300 ng/dl were excluded from the study. Many of these males were clearly hypo gonadal and would have benefitted from appropriate therapy.

There have been multiple studies demonstrating that testosterone administered to men will result in an increased blood flow to the coronary arteries and a decrease in plaque and inflammation in the coronary arteries. Based on **BioTE Medical** data from the treatment of over 10 thousand male patients and after optimization of testosterone levels in hypo gonadal males from 35-78 years of age, with or without heart disease, there was no increased risk of cardiovascular disease.

It is time for us to finally recognize the difference between the heavily advertised synthetic products from "Big Pharma" and the untold story regarding the benefits of **bio-identical hormone therapy**. It is also critical that we hold medical studies accountable to present complete information that takes into consideration all modalities that are currently available to patients.

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