

**EMBARGOED UNTIL WEDNESDAY, May 14, 2014, 800 AM ET**

**Androgen Study Group Urges FDA to Deny Public Citizen's Petition  
to Add Black Box Warning to Testosterone Products**

*The two studies alleging increased cardiovascular risks with testosterone therapy "are so flawed that they represent non-science, or its close cousin- nonsense." Comprehensive review of studies has been submitted to FDA. Number of studies showing beneficial versus harmful effects was 46 to 0. Assertions of cardiovascular risk with testosterone are therefore "akin to asserting that insulin causes diabetic complications or Viagra causes erectile dysfunction." Androgen Study Group calls on FDA to calm false public health fears. "There is no fire in the theater."*

**Boston, MA, May 14, 2014** – The Androgen Study Group has responded to the petition by Public Citizen to the Food and Drug Administration (FDA) to add black box warnings and other restrictions on testosterone products, urging the FDA to reject any restrictions based on cardiovascular (CV) risk. The response consists of an overview of the scientific literature accumulated over the last 30 years that strongly supports a beneficial effect of testosterone on CV issues, a detailed analysis of the recent studies that reported increased risks, and two appendices with eight tables that summarize the relationship of testosterone on various CV items such as mortality, and known risk factors such as obesity and blood sugar control. The response to FDA is available [HERE \(INSERT HYPERLINK\)](#).

Public Citizen cited only four studies to support its petition, none of which, upon inspection, provides any serious indication of increased risk. It completely ignores an extensive body of research literature spanning more than thirty years that demonstrates a strong relationship between CV risks and *T deficiency*, as well as *improvements* in CV risk factors and outcomes with T therapy.

The two recent publications that precipitated concerns regarding increased CV risk with T therapy are without scientific merit. One, by Vigen et al published in the Journal of the American Medical Association, has already been discredited, with two corrections since its original publication, including a series of data errors so large that 29 medical societies and more than 160 distinguished medical scholars from around the world have called for its retraction. Those errors included a numerical error of greater than 1000 men in one group, an error of greater than 900 men in a second group, and astonishingly, the discovery that nearly 10% of the all-male study was comprised of women. The second study, by Finkle et al published in PLoS One, reported *lower than expected rates of myocardial infarction* associated with testosterone prescriptions, and lacked a control group, so that it was unable to provide any indication whether observed rates of CV events were increased, decreased, or unchanged due to T therapy.

Testosterone deficiency, also called hypogonadism, or low T, is common, and causes a variety of troubling symptoms, including fatigue, depressed mood, muscle loss, increased fat, and

reduced sexual desire and performance. Martin Miner, MD, member of the Androgen Study Group and Co-director of the Men's Health Center in Providence, Rhode Island, added, "Testosterone deficiency has been shown in dozens of study to be associated with increased mortality, atherosclerosis, decreased blood sugar control, and osteoporosis. In fact, the association of *T deficiency* with CV and metabolic diseases has been projected to contribute to the annual development of approximately 1.3 million new cases of cardiovascular disease, 1.1 million new cases of diabetes, and over 600,000 osteoporosis-related fractures. Over a 20-year period, T deficiency has been estimated to be directly responsible for approximately \$113–\$313 billion in inflation-adjusted U.S. health care expenditures. Men aged 20–79 years at baseline with low T levels had 29% higher number of outpatient visits and 38% higher outpatient costs at 5-year follow up."

Mohit Khera, MD, Associate Professor of Urology at Baylor College of Medicine, added, "If you add up the studies that looked at the effect of higher testosterone on cardiovascular issues like mortality, coronary artery disease, carotid plaque thickness, obesity, fat mass, and blood sugar control, as we did in the tables in our FDA submission, the score for beneficial effects versus negative effects was 46 to 0 in favor of testosterone. The claim that T therapy contributes to CV risks and therefore requires a black box warning or other restrictive measures turns science upside-down. It is akin to asserting that insulin causes diabetic complications or that Viagra causes erectile dysfunction."

"The two studies that allegedly show increased risk with testosterone therapy are so flawed that they represent non-science, or its close cousin, nonsense," said Abraham Morgentaler, MD, Chairman of the Androgen Study Group, and Founder, Men's Health Boston. "The FDA has an obligation to calm public health fears over this false risk. Physicians and the consumer have been duped by medical journals choosing sensationalism over responsibility, by anti-pharma zealots, plaintiff attorneys, and by a media unwilling to express an ounce of skepticism when study findings make no sense. To scare men away from this valuable treatment based on such absurdly weak evidence is as reprehensible as yelling 'Fire' in a crowded theater. There is no fire in the theater, and the FDA has a responsibility to say so. With a bullhorn."

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### **About The Androgen Study Group (ASG)**

The Androgen Study Group is a multidisciplinary group of clinicians and researchers dedicated to education and accurate reporting on testosterone deficiency in men and its treatment.

For more information, go to [www.androgenstudygroup.org](http://www.androgenstudygroup.org).

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