

**Statement of the American Urological Association   
to the Advisory Committee of the U.S. Food and Drug Administration**

*Presented by Dr. Ajay Nangia on September 17, 2014*

The American Urological Association (AUA), representing more than 90% of the practicing urologists in the United States, strives to promote the highest standards of clinical urological care through education, research, clinical practice guidelines, and healthcare policies. Therefore, the AUA thanks the FDA for this hearing and welcomes the opportunity to increase awareness that testosterone replacement therapy, which we will call T-therapy, has, just like any other pharmacological treatment, potential risks.

The volume of testosterone use has increased dramatically recently. Why might this be? First, the association of testosterone deficiency with several common conditions – such as obesity, osteoporosis, muscle wasting and diabetes – is becoming increasingly apparent. Second, there are new delivery methods for testosterone, which are often preferred by patients. We suspect that this combination of increased awareness and more attractive delivery methods have much to do with the increased use of T-therapy. The dramatic increases in obesity, diabetes and metabolic syndrome are a larger problem. Chronic health issues of men and general health of men are ongoing concerns. The increasing evidence about the association with testosterone as a cause or effect of these issues has further highlighted that the health status of men in this nation encompasses more than just testosterone replacement, and this perspective should be our focus.

In February of 2014 the AUA issued a position statement on T-therapy. This document was shared with the committee in our written statement and we refer you to that report for more information. An important part of this document was the call for rigorous testing before starting T-therapy, thorough discussion of potential risks of T-therapy, and appropriate surveillance for patients on T-therapy, including ongoing assessment of side effects. Education may be more effective in guiding the appropriate use of T-therapy than labeling changes.

We summarize our position with 2 distinct points:

1. T-therapy is effective. It has been on the market for 40 years with FDA approval and millions of prescriptions have been written with hundreds of thousands of patients treated. If used appropriately according to the accepted indications, which the AUA always advocates, T-therapy can improve patients’ metabolic and general health. T-therapy used in the setting of documented low biochemical testosterone level together with signs and symptoms of hypogonadism is appropriate. T-therapy for low or low normal biochemical testosterone level without signs or symptoms of hypogonadism, or T-therapy for symptoms suggesting hypogonadism but without biochemical confirmation, is not supported by published literature. The AUA is committed to continuing its educational efforts on the proper use of T-therapy. In fact, we are in the planning stages of creating a clinical practice guideline on T-therapy, which will be based on rigorous systematic review of all available data, to more fully address this educational goal.
2. The AUA shares the FDA’s concern about recently published studies on cardiovascular risks and T-therapy, as patient safety is of utmost importance to the AUA. We need to strongly point out, however, that the studies associating T-therapy with increased cardiovascular risk are inconclusive and controversial. Given that the preponderance of evidence prior to these few recent studies had suggested just the opposite – that appropriate T-therapy reduces cardiovascular risk – we call for additional study before the FDA decides on any changes in labeling or restricts the availability of T-therapy.

Again, the AUA notes that the use of T-therapy has been longstanding, and, if used appropriately and according to recommendations, is effective. We understand and share the concerns that T-therapy may increase cardiovascular risk, but the AUA Board of Directors - on behalf of AUA members and patients that we as urologists treat - calls for additional study before conclusions are reached.

Finally, we thank the FDA for its ongoing work to promote both efficacy and patient safety in healthcare, and we look forward to opportunities to both work collaboratively with and serve as a reference for the FDA. Thank you.