

FDA bans marketing of testosterone for non-specific symptoms, concerned about possible heart effects

By ACSH Staff — March 4, 2015



The Federal Food & Drug Administration (FDA) yesterday issued

a mandate warning drug companies marketing testosterone supplements, via pills, gels or other methods, to change the label or indications for approved use. This change will now require specific disease indications for approved treatment, whereas doctors have been increasingly using the male hormone to attempt to improve general health, in the guise of a disease-construct called Low-T, including symptoms more consistent with aging: lethargy, diminished energy, low libido, depression.

However, as noted in the FDA advisory committee recommendations last September, there is little to no evidence that such treatment ameliorates any known condition. On the other hand, there have been several studies showing an increased risk of heart and other vascular problems (including stroke) associated with T-therapy, for instance: [here](#) [1], [here](#) [2] and [here](#) [3]. (On the other hand, at least one study we [discussed recently](#) [4] disagreed with the other findings).

ACSH's Dr. Gil Ross had this comment: The new disease, Low-T, seemed to me from the get-go to be a clever marketing ploy from the pharm industry to create an obvious (but unproven) condition and exploit it for enhanced sales. Really, who among us men over say 40 has not felt the drag of an aging *joie de vivre*, so to speak: diminished athletic reserve, anxiety/depression, flagging libido (both interest and performance)? And, doesn't the reduced production of that old reliable male hormone, testosterone, have *something* to do with all that? It must, right? So, let's dab a bit of T-gel on and get some mojo workin'! Well, sadly, the aging process is not so amenable to pharmaceutical intervention (as women learned from the panacea of hormone replacement).

Ah, but what s the harm in trying? Well, there is apparently a significant downside to the Low-T treatment story: actual, real disease, heart attack and stroke. So the FDA has taken appropriate action, reining in the remarkable increase in such treatments (or trying to anyway: doctors can still prescribe the stuff, but it will henceforth be off-label with all the ramifications for liability that entails).

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Links

[1] <http://acsh.org/2014/01/even-bad-news-supplements-testosterone-treatment-linked-heart-attacks/>

[2] <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3440621/>

[3] <http://acsh.org/2013/11/men-low-t-dont-buy-testosterone-supplement-hype/>

[4] <http://acsh.org/2014/07/testosterone-injections-associated-increased-heart-risk-older-men/>