FDA Strongly Rejects Citizens Petition for More Stringent Warnings on Testosterone Products!

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Two studies over the last nine months have raised much concern over the safety of testosterone replacement therapy. These studies essentially contradict over 30 years of medical literature.

Nonetheless, these studies have made headlines, spurred numerous lawsuits and have led to labeling changes on testosterone products, even though the data has not been validated.

On July 16th, 2014, in a surprising yet enlightening statement, the FDA rejected a Citizens Petition to add a "black box" warning to all testosterone products in addition to other demands included in the petition stating:

"After careful consideration, and, in light of the foregoing, we hereby deny your Petition in its entirety. FDA will continue to evaluate the cardiovascular risks of testosterone, and, if warranted, will take appropriate regulatory action to protect the public health when its evaluation has concluded."

In a rather lengthy response, the FDA echoed the concerns of many physicians, including the *Androgen Study Group*, in citing significant flaws/weaknesses in the recent studies that questioned the safety of testosterone therapy. Among the many study weaknesses, the FDA cited:

- Unclear statistical methods
- Conflicting results
- Overly broad definition of cardiovascular events
- No validated end points or lack of compliance data
- Incomplete or unavailable relevant laboratory data
- Short-term follow-up times precluding assessment of the potential benefits of long-term testosterone therapy.

As part of its continued monitoring, the FDA is awaiting the results of *The Testosterone Trial in Older Men* that is currently in progress. In addition, an advisory committee will be reviewing the topic again this fall.

When considering the results of new studies that contradict years of medical literature, one needs to be careful not to jump to conclusions, especially when it comes to the public health. These flawed studies represent a case in point of the media and lawyers creating near hysteria before the medical community has had a chance to sort out the truth. Neither lawyers nor the media have the expertise to interpret and scrutinize study data, and likely have other motives such as financial gain or a sensational news story.

At Cenegenics, we strive to keep you abreast of current topics so you can take control of your health and make informed decisions, not decisions based on fear or distorted rhetoric.

To view the FDA's denial response, see *FDA denial*. See the last 2 pages for summary statements.