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Physician Views: What impact has the controversy surrounding use of testosterone products had on urologists?

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Abstracts

The number of prescription written for testosterone replacement therapy has skyrocketed over the past couple decades thanks in no small measure to a concerted effort on the part of a handful of drugmakers to heighten awareness of hypogonadism – or 'Low T' as it is often referred to – through direct-to-consumer campaigns.

It should be noted that advertising alone is not the only driving force behind the significant increase in use of testosterone products, as data released recently by the Massachusetts Male Aging Study suggest that almost 2.5 million men ages 40 to 69 suffer from hypogonadism, with just under 500 000 new cases emerging each year.

Questions have long been asked about whether and at what level of endogenous testosterone production does 'Low T' become a condition requiring treatment. More recently, however, the debate about the potential benefits of testosterone therapy took on a new urgency after a published study late last year pointed to links between use of the products and an increased risk of cardiovascular events.

Sales of testosterone products from companies including AbbVie and Eli Lilly topped $2 billion in 2012 and, at the time, analysts were still predicting rapid growth of the market.

More recently, the FDA said in June that all testosterone-based therapies should carry warnings of a risk of blood clots, while also scheduling an advisory panel meeting to evaluate the adverse cardiovascular effects of testosterone replacement therapies that will take place on September 17.

Indeed, lingering questions about potential overuse of the products and, perhaps more

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importantly, concern about possible safety risks appear to have begun taking a toll on the growth prospects.

Thus, to better understand how the marketplace for testosterone replacement therapies is evolving, FirstWord is this week polling US and EU5-based urologists. Specifically we are asking them.

> In your opinion, the number of patients being treated for 'Low-T' (or hypogonadism) is too low or too high?
>
> How has the number of men interested in receiving testosterone therapy changed over the past 8 to 12 months?
>
> How has the controversy surrounding use of testosterone products (in particular the FDA's announcement that it would be launching an investigation into a possible cardiovascular safety signal) affected your prescribing patterns?
>
> On a scale of 1 to 10, how concerned are you about the evidence available suggesting CV risks associated with testosterone products?
>
> Marketed testosterone products are delivered transdermally or by injections. A new (still experimental) product – an oral pill containing an inactivated version of testosterone that becomes activated by enzymes in the body, thus being quicker, easier and avoiding the risk of transference to a woman or child – is in Phase IV trials. Given the various advantages (while also taking into account its similar pharmacological activity once activated), might you be any more/less likely to use this product versus the transdermal/injectable options?

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