FDA to Review Safety of Testosterone Therapy

The U.S. Food and Drug Administration (FDA) has announced its plan to reassess the safety of FDA-approved testosterone products.

The decision stems from concerns over two recent studies that suggested increased risk of heart attack, stroke, and death for men on testosterone therapy.

Testosterone is a hormone produced by a man’s testes. It contributes to sex drive, sperm production, muscle mass, and strength. It also gives men their secondary sex characteristics, such as facial hair and a deep voice.

It’s natural for men’s testosterone levels to naturally decline as they get older. But some men have low testosterone because of a medical condition called hypogonadism. Hypogonadism can occur when a man’s testes don’t work properly. It can also happen when there are problems with the hypothalamus and the pituitary gland, both located in the brain. These areas contribute to testosterone production.

Many men with hypogonadism go on testosterone replacement therapy. Testosterone can be administered through injections, applied as a gel or patch, or spread on the upper gum or inner cheek.

The first study to cause concern was published in November 2013 in the Journal of the American Medical Association. Approximately 8,700 participants with low testosterone were evaluated for heart disease with an imaging test called a coronary angiography. Around 1,200 of the men were later prescribed testosterone therapy. The researchers found that the men on testosterone developed a 30% increase in the risk of stroke, heart attack, and death.

The second study was published in PLOS One in January 2014. This work looked at the history of heart problems among 55,593 men who took testosterone. Specifically, the researchers analyzed the men’s health one year prior to starting testosterone therapy and 90 days after treatment began.

They found that participants age 65 and over were twice as likely to have a heart attack in the 90 days following the start of testosterone treatment. Men younger than 65 who had a history of heart disease saw their risk increase two to three times. Younger men with no history of heart disease did not have increased risk.
In a safety announcement dated January 31, 2014, the FDA stated, “At this time, FDA has not concluded that FDA-approved testosterone treatment increases the risk of stroke, heart attack, or death. Patients should not stop taking prescribed testosterone products without first discussing any questions or concerns with their health care professionals. Health care professionals should consider whether the benefits of FDA-approved testosterone treatment is likely to exceed the potential risks of treatment.”

The FDA will announce its final conclusions and recommendations after it finishes the investigation.

**Resources**

*HealthDay*

Doheny, Kathleen

“Testosterone Therapy Might Increase Heart Attack Risk: Study”

(January 29, 2014)


*Journal of the American Medical Association*

Vigen, Rebecca, MD, MSCS, et al.

“Association of Testosterone Therapy With Mortality, Myocardial Infarction, and Stroke in Men With Low Testosterone Levels”

(Full-text. November 6, 2013)


*MedPage Today*

Fiore, Kristina

“FDA to Investigate Testosterone Risk”

(January 31, 2014)

**Medscape**

O’Riordan, Michael

“FDA Now Investigating CVD Risks With Testosterone Therapy”

(January 31, 2014)


**The New York Times**

O’Connor, Anahad

“New Concern About Testosterone and Heart Risks”

(January 29, 2014)