

US regulators probing cardio risks in testosterone products

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US federal regulators said Friday they were investigating products containing testosterone after recent studies suggested a higher risk of strokes and heart attacks in men being treated with the hormone.

The Food and Drug Administration stressed, however, that it has "not concluded that FDA-approved testosterone treatment increases the risk of stroke, <u>heart attack</u> or death."

"FDA is providing this alert while it continues to evaluate the information from these studies and other available data," it said in a safety alert, referring to two related studies.

Patients undergoing <u>testosterone therapy</u> should not stop their treatment without consulting their physician first, the FDA recommended.

Health care professionals were also asked to consider whether the benefits of FDA-approved testosterone treatment were likely to outweigh the possible risk of treatment.

The announcement followed <u>publication of a study on Wednesday</u> by the *PLOS ONE* science journal suggesting that men aged 65 and older being treated with testosterone were twice as likely to suffer heart attacks in the month after they began treatment.

The study, which analyzed findings from 56,000 men in the United States between 2008 and 2010, also revealed a sharply increased risk



among younger men with a history of heart disease.

In November, a separate clinical study in the *Journal of the American Medical Association* reported that older men using testosterone, including many with a history of heart problems, faced a 30 percent greater chance of mortality, heart attack or cardiovascular event.

A US government-funded study to determine whether men using <u>testosterone gel</u> to build muscle and increase strength was halted in 2009 after the high rate of cardiovascular problems related to the treatment.

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