

'Low T' therapy has yet to be proven: FDA

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Agency orders makers of popular testosterone supplements to conduct clinical trials.

(HealthDay)—Testosterone supplements have long been marketed to aging men as a fountain of youth and virility, but there is still no proof they are safe or effective, according to the U.S. Food and Drug Administration.

Writing in the Aug. 20 edition of the *New England Journal of Medicine*, FDA officials said that only controlled [clinical trials](#) can show whether [men](#) benefit from treatment to reverse age-related dips in testosterone.

The agency is now requiring product manufacturers to conduct those trials.

As it stands, testosterone supplements are approved only for men with certain medical conditions that cause abnormally low levels of the hormone—such as damage to brain areas that control testosterone production.

But once the FDA approves a drug, doctors are free to prescribe it as they see fit. And most American men on [testosterone therapy](#) have no clear medical condition; they're using it to counter the aging process, the researchers said.

Between 2009 and 2013, the number of U.S. men on testosterone shot up from 1.3 million to 2.3 million, according to the FDA. And the most common reason, the agency says, is the vague diagnosis of "testicular hypofunction, not

elsewhere classified."

That explosion in testosterone use has occurred despite a lack of evidence showing it is effective. The surge has been attributed to an aggressive marketing campaign by manufacturers alerting men to the potential effects of "low T," such as fatigue, sexual dysfunction, declining muscle mass and gains in body fat.

"The benefits and risks of testosterone therapy have not been established for the treatment of men who have [low testosterone levels](#) due to aging, even if there are symptoms that seem related to the low testosterone," said Dr. Christine Nguyen, lead author of the FDA report and the agency's deputy director of safety.

Typically, a man's [testosterone levels](#) slowly decline with age. And there is a "rough correlation" between that decline and symptoms such as sexual dysfunction, said Dr. Bradley Anawalt, an endocrinologist and professor of medicine at the University of Washington, in Seattle.

But it's not clear whether "low T" or other factors—such as chronic health conditions, medications or the aging process itself—are to blame. And it's unlikely, Anawalt said, that men with modestly low testosterone levels would get any benefit from supplements.

What's more, concerns persist that testosterone supplements increase a man's risk of heart attack or stroke. Last March, the FDA started requiring all prescription testosterone products to carry a warning about those potential hazards.

Still, the evidence is mixed. One recent study found that men given a [testosterone gel](#) were no more likely to develop hardening of the heart arteries over three years, compared to men given a placebo gel that contained no medicine.

The study did not look at rates of heart attack or stroke, however. Only further clinical trials can

show whether those risks are real, the FDA says.

There are other issues, as well. For one, Anawalt said, an older man's testosterone is considered "low" if it falls below the normal range for a healthy young man. There are no standards on normal levels for specific age groups.

"It's just been assumed that the normal range for young men applies to older men, too," Anawalt said.

What's more, FDA research has found that many men do not have any [testosterone testing](#) done before getting a prescription for supplements.

And while it is not clear if testosterone is dangerous for men's hearts, there's also little evidence that it benefits their well-being, Nguyen pointed out.

The recent study that found no ill effects on men's heart arteries also found no improvement in sexual function.

Anawalt said that for men with medical conditions that limit testosterone production, it's "pretty clear" that supplements can be helpful. "The question remains," he said, "what do you do with the much larger group of men who have 'low T' related to aging?"

Based on what's known, Anawalt said, supplements are "unlikely to do much" for most men whose [testosterone](#) dips solely due to age.

More information: The FDA has more information on [testosterone supplements](#).

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