FDA: Little evidence to support testosterone drugs (Update)

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The Food and Drug Administration says there is little evidence that testosterone-boosting drugs taken by millions of American men are beneficial, though the agency is also unconvinced by studies suggesting the hormone carries serious risks.

The agency posted its review online Wednesday ahead of a public meeting to discuss the benefits and risks of treatments that raise levels of the male hormone. Regulators agreed to convene the September 17 meeting after two federally funded studies found links between testosterone therapy and heart problems in men.

The scrutiny comes amid an industry marketing blitz for new pills, patches and formulations that has transformed testosterone a multibillion-dollar market. Advertisements for prescription gels like Fortesta and Androgel promise aging men relief from "Low-T," a condition they link to low libido, fatigue and weight gain.

But FDA reviewers state that "the need to replace testosterone in these older men remains debatable." While testosterone levels naturally decline after age 40, it's unclear whether those lower levels actually lead to the signs commonly associated with aging, including decreased energy and loss of muscle.

The FDA first approved testosterone injections in the 1950s for men who had been diagnosed with hypogonadism, a form of abnormally low testosterone caused by injury or medical illness.

But the recent advertising push is focused on otherwise healthy men who simply have lower-than-normal levels of testosterone.

The FDA memo calls testosterone use in these patients "controversial" and notes that "there are no reliable data on the benefit in such a population."

The agency will ask its panel of outside experts this month whether the prescribing information on testosterone drugs should be revised to focus on a narrower group of patients.

The panelists will also be asked to weigh in on two recent studies that showed higher rates of cardiovascular problems in men using testosterone. A U.S. Veterans Affairs study published in November 2013 showed a 30 percent increase in stroke, heart attack and death among older men taking testosterone. In January, another federally funded study of 45,000 men with an existing heart condition suggested testosterone therapy could double the risk of heart attacks in men 65 and older.

But in its review, the FDA notes that two other studies have associated testosterone with longevity. According to the agency review, the available studies "do not provide convincing evidence that testosterone replacement therapy is associated with adverse cardiovascular events."

According to the review documents, FDA will ask its experts whether drugmakers should be required to conduct long-term follow-up studies to assess heart risks with testosterone drugs.

Roughly 2.3 million U.S. patients received a prescription for testosterone last year, up 77 percent from 2010, according to FDA figures. The agency notes that more than 20 percent of patients who received a prescription did not have any record that their testosterone levels were measured.

Consumer advocacy group Public Citizen said the FDA's review downplays the evidence of heart risks shown across multiple studies. In February the group petitioned the FDA to add a boxed warning—the most serious type—to all testosterone drugs about potential heart risks. Although the FDA rejected that proposal, the group's Dr. Sidney Wolfe says he still expects the recent studies about heart risks to be added to testosterone's label.

"There will be a warning and once it happens the prescribing will drop way down, and that will be to the betterment of the public health in this country," said Wolfe, of Public Citizen's health group.

Wolfe noted that prescriptions for Androgel, the best-selling testosterone drug from Abbott Laboratories, have already fallen 23 percent since July 2013.

In a separate memo, 12 manufacturers of testosterone drugs acknowledged that there are no long-term studies of testosterone therapy, making it difficult to gauge their benefits and risks. Still the companies pledged to educate doctors and patients about the drugs "so that they can make informed treatment decisions."

The group includes Abbvie, Eli Lilly & Co., Endo Pharmaceuticals and Upshur-Smith Laboratories.