

Telehealth sites promise cure for 'male menopause' despite FDA ban on off-label ads

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Credit: CC0 Public Domain

Online stores sprang up during the COVID-19 pandemic's telehealth boom touting testosterone as a cure-all for men's age-related illnesses—despite FDA rules issued years ago restricting such "low



testosterone" advertising.

In ads on Google, Facebook, and elsewhere, testosterone telemedicine websites may promise a quick fix for sluggishness and low libido in men. But evidence for that is lacking, physicians said, and the midlife malaise for which testosterone is being touted as a solution is more likely caused by chronic medical conditions, poor diet, or a sedentary lifestyle. In fact, doctors urge caution— and the FDA recommends that all testosterone supplements carry a warning that they may increase the risk of heart attack and stroke.

Valid medical reasons do exist for treating some men with testosterone. The hormone as a medication has existed for decades, and today's patients include men with hypogonadism, some transgender men who use it to help transition physically, and, sometimes, women dealing with menopausal symptoms. It has also been used for decades by bodybuilders and athletes to enhance strength.

However, online dispensaries can overplay the idea of what is sometimes called "male menopause," or even "manopause," to drive sales of highly profitable testosterone-boosting injectables, often ignoring safety guidelines that should prevent healthy men from using the hormone. Some of the websites target military veterans.

"I have seen ads online that do cross the line," said Steven Nissen, a physician and the chief academic officer for the Heart, Vascular, and Thoracic Institute at the Cleveland Clinic. "For mood and low energy, prescribing testosterone provides little to no benefit. They are promoting testosterone for indications that are not on the label."

Testosterone telehealth websites almost all cite one study published in 2002 by New England Research Institutes scientists who found testosterone levels drop 1% a year in men over 40. Stefan Schlatt,



director of the Center for Reproductive Medicine and Andrology at the University of Muenster in Germany, said the data behind the statistic included older men in deteriorating health whose levels declined because of illnesses.

"Healthy men do not show a drop," he said.

That 2002 study led to a flood of "low-T" ads on U.S. television—ads that were later banned by the FDA in a 2015 ruling that accused the pharmaceutical industry of exaggerating the low-T phenomenon to scare men into buying drugs. According to another study, the market for testosterone supplements stood at \$1.85 billion in 2023.

The deluge of ads "has fueled demand for a largely uninsured product, allowing for high markups," said Geoffrey Joyce, director of health policy at the USC Schaeffer Center for Health Policy & Economics and a research associate at the National Bureau of Economic Research. "The primary driver is manufactured demand."

Barbara Mintzes, a professor of evidence-based pharmaceutical policy at the University of Sydney's Charles Perkins Center in Australia, said low testosterone should really be seen as a sign of a condition that needs to be treated. She said diabetes, heart disease, high blood pressure, obesity, exposure to toxic chemicals like PFAS, and stress can all reduce testosterone levels.

Several websites reviewed by KFF Health News brand themselves as news and fitness magazines, with advertisements embedded in articles steering readers toward order forms for testosterone replacement therapy, shorthanded as TRT. The sites' prices for TRT range from \$120 to \$135 a month, not including initial mail-back blood tests for around \$60. Some sites promise increased libido and reduced stomach fat.



Male Excel's ads on Google, for example, say TRT "improves mood" and "restores vitality." And its site says testosterone treatment will provide "muscular definition," "weight loss," "explosive drive," "deeper sleep," and "restored energy" above a link to a free assessment on its online telehealth platform. Craig Larsen, the company's CEO, did not reply to several attempts to contact him by phone and email.

Both Male Excel and Hone Health are among the sites that pitch to military veterans. Hone Health included a video of a veteran who said he was refused testosterone treatment by a Department of Veterans Affairs hospital.

Saad Alam, CEO and co-founder of Hone, said that his company is what he called a "conservative" player in the market. He said that Hone prescribes only to men who are hypogonadal and tests men every 90 days, unlike other companies that operate telehealth websites as what he called a "cash grab."

"I agree that patients should be treated by their doctors. But the U.S. medical system isn't at a point where it can service men who have this problem, and some endocrinologists would rather treat patients who are higher-profit," Hone said. "That's why people are coming to us."

One popular form of TRT is injectable testosterone cypionate. According to the Medicare average sales price database, it costs \$0.027 per milligram. Online purveyors who sell the drug directly to consumers in 200 mg/mL vials for an average price of \$129 per month are charging the equivalent of \$1.55 per mg—a markup of more than 50 times the average Medicare price.

According to a 2022 study, the TRT telehealth websites create a way to circumvent doctors who refuse to prescribe the hormone. In that study, Justin Dubin, a urologist at the Memorial Healthcare System in Florida,



posed as an online mystery shopper. He reported an above-normal testosterone level, and stated his desire to start a family, even though such therapy can curb sperm production. But six of the seven unnamed online TRT clinics prescribed him testosterone via a medical professional.

"And that's concerning," Dubin said. "Telemedicine helps men with hypogonadism who might be too embarrassed to discuss erectile dysfunction. But we need to do a better job of understanding the appropriateness of care."

Still, while the FDA doesn't allow off-label marketing, it does allow such off-label prescriptions.

Off-label use of testosterone replacement has become especially commonplace among veterans. And among male service members who received TRT in 2017, fewer than half met the <u>clinical practice</u> <u>guidelines</u>, according to a report by the U.S. military.

Phil Palmer, a 41-year-old Marine Corps veteran who lives outside Charleston, South Carolina, said he pays out-of-pocket for bloodwork and prescriptions for a pellet skin-implant form of testosterone and for clomiphene, a drug that can help counter the male infertility that is a side effect of testosterone treatment. He said the treatment appeals to him and other veterans dealing with the aftermath of military service.

"The environment we served in and stress levels have a lot to do with it," Palmer said. "We were exposed to burn pits. The military doesn't teach you to eat well—we ate a lot of processed food."

In medical settings, TRT can speed recovery of soldiers who have bone density issues or <u>spinal cord injuries</u>, said Mark Peterson, a professor of physical medicine and rehabilitation at the University of Michigan



Medical School. But, he said, "for men in the normal-T range, using an online prescription to buy testosterone to reduce stomach fat can be counterproductive."

Those who use it also risk having to take testosterone medication indefinitely, because TRT can cause the body to cease its own production of the hormone.

Palmer, who founded a nonprofit that helps veterans heal through exercise, nutrition, and mentorship, said the medication has been helpful for him but urges fellow veterans to seek care from their doctors rather than what he called "bro science" websites touting testosterone.

"It's not a magic pill," he said.

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