Caution Urged on Androgen Therapy for Women

BY CHRISTINE KIGLOR
Contributing Writer

The Endocrine Society is sounding a warning word of caution about an

drogen therapy with a new clinical practice guideline that recommends against
diagnosing and treating androgen deficiency. The guidelines state the lack of a well-defined
clinical syndrome and the lack of normative data on total or free testosterone levels across the life span as reasons why a diagnosis should not be made.

This is a point of concern, 20 years after the American Diabetes Association issued practice recommendations that do not recommend androgen therapy for older men with low testosterone levels.

The new guideline on androgen deficiency in women has a tone and reach that differs from the less-conservative “andro
drogen deficiency” section in the third edition of the Endocrine Society’s 2001 guideline—updated in 2005. This and the guideline’s tone and reach reflect a similar U-turn at a different time, at a different place, said Dr. Steven Petak, president of the American Association of Clinical Endocrinologists (AACE). A decade ago, the FDA issued a warning about androgen therapy, and now it has been revised and recom
dicated. The new guideline on androgen deficiency in men advises physicians to offer testosterone therapy on an individual basis to older men with consistently low testosterone levels on more than one occasion and within significant symptoms of androgen deficiency.

The guideline advises against the use of androgen therapy in the general population because of a lack of consensus on the case definition and a lack of data on the public health impact of androgen deficiency.

To establish the diagnosis of androgen deficiency in men, a reliable assay should be used to measure the median total testosterone level. This should be confirmed either by repeating the measurement of morning total testosterone or by measuring the free or bioavailable testosterone level. These findings on the role of androgen therapy in the general population because of a lack of consensus on the case definition and a lack of data on the public health impact of androgen deficiency.

Testosterone therapy is appropriate in symptomatic men who have classic androgen deficiency and low testosterone levels, say the guidelines.

It should be used to induce and maintain secondary sex characteristics and to improve sexual function, sense of well-being, muscle mass, strength, and bone mineral density.

Testosterone therapy is not appropriate for women due to its serious side effects and potential health risks.

Even With Men, Go Slow With Androgen Therapy

BY ELIZABETH MECHCATT
Senior Writer

The sale of products that are misrepresented as cures or treatments for diabetes and the Internet sites that advertise these products are the target of a campaign launched by U.S., Mexican, and Canadian government agencies. The Food and Drug Administration and the Federal Trade Commission (FTC) announced in a statement that the FDA had issued 24 warning letters to companies marketing dietary supplements with claims that the products treated, cured, prevented, or mitigated diabetes. To date, about 180 letters and other advisories have been sent to online outlets in the three countries as a result of the campaign.

The FTC also announced a new campaign aimed at educating consumers about how to avoid falling for sham diabetes cures. Included in an example of a Web site promoting a phony product called Glucabate.

Great source of information, but also it is a billboard for ads that promise miracle cures for diabetes and other serious diseases, Lynda Barnes, director of the FTC’s Bureau of Consumer Protection, said in a statement.

“People need to think twice before trusting their health to products that are not supported by scientific evidence,” Barnes said. “And when they do shop, they should look for the seal of approval from a reputable organization.”

Among the claims made on the Web site, according to the FTC, is that the product is advertised as containing extract from Cau
casian blueberry leaves.” The letter that says marketing this product with the therapeutic claims that appear on its Web site establishes it as a drug and, therefore, violates the Federal Food, Drug, and Cosmetic Act. Among the claims on the Web site, according to the letter, is that the statement that Caucasian blueberry leaves have been “effectively used to manage the effects of diabetes” for centuries.

FDA Targets Firms Marketing Sham Diabetes Products on the Internet

BY E LIZABETH MECHCATT
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Warning on Counterfeit Glucose Tests Stresses Misinformation

BY ELIZABETH MECHCATT
Senior Writer

Some blood glucose test strips being sold in the United States are counterfeit and potentially could provide patients with incorrect information on blood glucose values, according to an alert issued by the Food and Drug Administration (FDA).

Certain lots of two types of test strips used with different models of OneTouch–brand blood glucose monitors have been found to be counterfeit and are being voluntarily recalled by the manufacturer, LifeScan Inc. The counterfeit test strips are:

| OneTouch Basic/Profile (lot #272894A, 2619392, or 2606340) test strips. (The outer cartons of these strips have English, Greek and Portuguese text; and only 50 count packages are affected.)
| OneTouch Ultra (lot #2691191) test strips. (The outer cartons of these strips have English, French and Italian text; and only 50 count packages are affected.)

The FDA is advising consumers to stop using these counterfeit strips if they have purchased them, replace the strips immediately, and call their physicians. The company is advising customers to contact their original source of the strips for restitution.

The FDA, which is investigating this case, has not received any reports of injuries related to the counterfeit strips but encourages physicians and others to report any adverse reactions associated with the use of this product and/or quality problems to the FDA’s MedWatch program at 800-332-1088, or www.fda.gov/medwatch.

—Elizabeth Mechcatt