Many men are being treated with testosterone when there is not enough information about its risks, says a doctor in a letter to The Lancet Diabetes and Endocrinology journal. Dr. Stephanie Page, an endocrinologist at the University of Washington and Harborview Medical Center in Seattle, says that there needs to be more clinical trials to evaluate the benefits versus risks of testosterone therapy. She noted that larger and longer studies are necessary and that failing to do this would do men's health a disservice.

Testosterone is a billion dollar industry, probably fuelled partly by direct to consumer advertising and some degree of overprescription, Dr. Page states. Physicians need to discuss with their patients that we simply do not fully understand the risks associated with testosterone use in older men, and use conservative treatment guidelines such as those provided by the Endocrine Society to guide therapeutic decisions.

Page's letter comes in light of recent safety concerns over testosterone. Previously, we reported that the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) are investigating the cardiovascular risks associated with testosterone drugs. The reviews are based on two studies suggesting that use of testosterone therapy can increase the risks of heart attack and stroke. The most recent study, published January in PLoS One, found that use of testosterone drugs was associated with an increased risk of heart attack in older men and younger men with a pre-existing heart condition. In November, a study published in the Journal of the American Medical Association (JAMA) found that testosterone therapy was linked to a higher risk of stroke, heart attack and death.

Testosterone is the hormone largely responsible for the development of male sex characteristics. According to Mayo Clinic, testosterone levels peak in adolescence and early adulthood and slowly decline after the age of 30. Some men have a medical condition that causes them to produce an abnormally low amount of testosterone (hypogonadism); the FDA has only approved testosterone therapy for this use. Drug companies, however, have touted testosterone therapy as a way to treat low-T stating that it could help with symptoms such as low sex drive and low energy.

A consumer advocacy group, Public Citizen, said in February that the FDA should add a black box label to testosterone drugs. A black box label is the agency's most serious warning notification. Public Citizen said that there have been mounting evidence of the drugs' heart risks since 2010, and a recent analysis of 27 studies help confirm these risks.

Lawsuits have already been filed over the cardiovascular issues allegedly caused by Low-T drugs. Several lawsuits filed in the U.S. District Court for the Northern District of Illinois allege that the medication AndroGel caused heart attacks, heart failure and stroke. None of the men suing over the testosterone drug had a previous history of heart disease.

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Doctor Says Studies of Low T Testosterone Treatment are Urgently Needed

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EMA also Investigates Link between Testosterone Drugs and Heart Problems
April 15, 2014
Posted on April 15, 2014 by steve | Comments Off

The European Medicines Agency (EMA) is reviewing the cardiovascular risks of testosterone drugs, MedPage Today reports. Like the U.S. Food and Drug Administration (FDA) the agency is basing its investigation on two recent studies showing that the drugs are associated with a higher risk of heart attack and cardiovascular death. The review was prompted by the Estonian State Agency of Medicines and will be conducted by the EMAs Pharmacovigilance Risk Assesmer Committee (PRAC).

The most recent study, published January in PLoS One, showed that testosterone therapy increased the risk of heart attack in older men and younger men who had pre-existing heart condition. In November, the Journal of the American Medical Association (JAMA) published a study linking testosterone therapy to an increased ri of stroke, heart attack and death.

The FDA announced its review in late January. The agency pointed out that that testosterone drugs are only approved for men who have low levels of testosterone due to a medical condition. In recent years, sales of testosterone medications have been on the rise, largely due to drug companies who tout testosterone as a way I treat Low-T, which can manifest as lower sex drive or loss of energy. The FDA has not approved testosterone drugs to treat Low-T.

Public Citizen, a consumer advocacy group, petitioned for the FDA to add a black box warning to the drugs label in February. The black box warning is the agencies most serious warning. Public Citizen said that its petition was based on mounting evidence linking testosterone to cardiac risks since 2010, in addition to a recent analysis of 27 studies over the course of at least two decades, according to Reuters.

A growing body of evidence suggests Low-T drugs are associated with pulmonary embolism, deep vein thrombosis (DVT), stroke, heart attack and other cardiovascular injuries, and death. Since the FDA launched its investigation there have been mounting lawsuits alleging the drugs caused heart problems. Four lawsuits were filed over the testosterone medication AndroGel. The suits, which were filed in the U.S. District Court, Northern District of Illinois, alleging that AndroG caused the men to suffer from heart attacks, heart failure and stroke; none of the plaintiffs had a prior history of heart disease.

Visit link:
EMA also Investigates Link between Testosterone Drugs and Heart Problems

New Testosterone Drug OK'd by FDA Amid Controversy
March 11, 2014
Posted on March 11, 2014 by fred | Comments Off

WebMD News from HealthDay

March 10, 2014 — A controversial new drug for men with low testosterone has been approved by the U.S. Food and Drug Administration.

Aveed, a long-acting testosterone injection that’s taken once very 10 weeks, is expected to be available this month, according to Irish drugmaker Endo Pharmaceuticals. Similar products need to be taken weekly or biweekly, CBS News/Associated Press reported.

The FDA should reverse its approval of Aveed, Public Citizen’s Health Research Group founder Dr. Sidney Wolfe said in a letter to the agency. He pointed out that a FDA panel of outside experts last April voted 9-9 on whether the drug was safe for treating low testosterone.

That vote came before a federal study suggested that testosterone therapy could double the risk of heart attack in men 65 and older, said Wolfe, who added that the vote result might have been against the drug if that information was known at the time.

In response to the study, the FDA said in January that it was reviewing the safety of testosterone drugs. Public Citizen says the FDA should make all testosterone drugs carry a black box warning about cardiovascular risks, CBS News/AP reported.
“The FDA’s current view is that the benefits of testosterone therapy, including Aveed, outweigh the known risks when used as directed in patients for whom the drug indicated,” said FDA spokeswoman Andrea Fischer.

Read the original here:
New Testosterone Drug OK’d by FDA Amid Controversy

Incoming search terms:

Despite Mounting Lawsuits and Injuries Associated with Approved Testosterone Drugs, FDA Approves Another Testosterone ...

The U.S. Food and Drug Administration (FDA) just announced its approval of Endo International Plcs Aveed, a drug it previously rejected not once, but three times. Aveed is a testosterone replacement therapy that is approved to treat male hypogonadism.

Male hypogonadism is a condition in which the male body produces low levels of testosterone. Testosterone is the male hormone responsible for maintaining muscle bulk, sexual function, and bone growth. Low levels of testosterone may lead to reduced libido, fatigue, and depression, according to Reuters.

Aveed was rejected for the third time last May, according to Reuters. The FDA indicated that, at that time, Endo needed to provide an improved plan to manage risks associated with the long-acting testosterone treatment. Aveed contains both testosterone and castor oil and the agency was concerned about the risks of castor oil leading to pulmonary blood vessel blockages and complications associated with post-injection reactions.

Current testosterone treatments include skin patches; short-acting injections; topical gels; and the buccal system, which involves application to the upper gum or inner cheek. Products include AbbVie Incs AndroGel, Androderm, Axiron, Bio-T-Gel, and Delatestryl. Endo International, previously known as Endo Health Solutions Inc., announced that its Aveed will be launching early this month, Reuters reported.

Meanwhile, the FDA recently issued a Drug Safety Communication in which it announced its investigation of increased stroke, heart attack, and death risks in men taking currently FDA-approved testosterone products, such as AndroGel. The agency also indicated that it is monitoring cardiac and death risks tied to testosterone products for approved uses and is re-assessing these risks following the publication of two separate research studies on the matter. Both studies suggest that an increased risk of cardiovascular events was seen in men prescribed and receiving testosterone therapy.

Public Citizen, a consumer advocacy group, has urged the FDA to increase the warnings about these risks on drugs labels, calling for the agency to add a Black Bo warning, the FDAs most serious warning, a prior Reuters report stated. According to the FDA, no approved testosterone product has been cleared for use in men diagnosed with low testosterone that is not linked to a medical condition. Medical conditions include the genetic failure of the testicles to produce testosterone, according to a previous Reuters report.

The first of the two studies was published in the Journal of the American Medical Association (JAMA) last November, and involved older men. The research suggested increased risks for stroke, heart attack, and death were seen in men prescribed testosterone therapy. The second study, published in journal, PLoS, also suggested increased risks for heart attack in older men, and in younger men diagnosed with a pre-existing heart disease.

Low-T drugs have been tied to a number of significant side effects, including pulmonary embolism, deep vein thrombosis (DVT), stroke, heart attack and other cardiovascular injuries, and death. In fact, since the FDAs announcement, four AndroGel lawsuits were filed in U.S. District Court, Northern District of Illinois. All of these lawsuits similarly allege that the use of AndroGel caused the men, all of who allege no prior history of cardiac disease, to suffer heart attacks, heart failure and stroke.

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Endo gets approval for long-acting testosterone
March 07, 2014
Posted on March 7, 2014 by admin | Comments Off

Article updated: 3/7/2014 8:14 AM

Associated Press

Drugmaker Endo Pharmaceuticals announced Thursday that it received U.S. approval for its long-acting testosterone injection Aveed, which joins a crowded field of hormone-boosting drugs aimed at aging American men.

The Irish drugmaker said the Food and Drug Administration approved Aveed for men with low testosterone, a condition sometimes associated with fatigue, weight gain and low libido. Endos injection is to be taken once every 10 weeks, versus weekly or biweekly dosing for currently available products. The company said in a statement it expects to launch the drug this month. The Dublin-based company already markets Fortesta, a prescription gel form of testosterone, the male hormone that begins to decline after age 40.

The FDA approval comes amid growing scrutiny of popular testosterone drugs.

In January the FDA said it was reviewing the safety of the drugs after a federal study of 45,000 patients suggested testosterone therapy could double the risk of heart attack in men 65 and older. Last month the consumer advocacy group Public Citizen called on FDA regulators to add a bold warning label about the cardiovascular risks to all testosterone drugs.

The approval was criticized by Public Citizens Health Research Group founder Dr. Sidney Wolfe, who sent a letter to the FDA Thursday asking it to reverse its decision. He noted that an FDA panel of outside advisers issued a split opinion on Aveeds safety last year, voting 9-9 on the question of whether the drug was safe f treatment of low testosterone. He adds that the meeting, held last April, did not include a discussion about heart risks.

It is likely, if not certain, that the vote against safety would have been even greater had there been a presentation and discussion of the cardiovascular risks known a that time, Wolfe states.

FDA spokeswoman Andrea Fischer said in a statement that the FDA is continuing its review of testosterone products, but there is no evidence that Aveeds risks are any greater than those of other testosterone drugs already on the market.

The FDAs current view is that the benefits of testosterone therapy, including Aveed, outweigh the known risks when used as directed in patients for whom the drug is indicated, Fischer said.

Excerpt from:
Endo gets approval for long-acting testosterone

Posted in Testosterone
Tagged a-bold-warning, a-federal-study, a-split-opinion, andrea-fischer, cardiovascular, consumer, drug, drugmaker-endo, generated, irish, january-the-fda, public-citizen, safety, testosterone

Despite Mounting Law Suits and Injuries Associated with Approved Testosterone Drugs, FDA Approves Another Testosterone ...
March 06, 2014
Posted on March 6, 2014 by steve | Comments Off

The U.S. Food and Drug Administration (FDA) just announced its approval of Endo International Pcs Aveed, a drug it previously rejected not once, but three times. Aveed is a testosterone replacement therapy that is approved to treat male hypogonadism.

Male hypogonadism is a condition in which the male body produces low levels of testosterone. Testosterone is the male hormone responsible for maintaining muscle bulk, sexual function, and bone growth. Low levels of testosterone may lead to reduced libido, fatigue, and depression, according to Reuters.

Aveed was rejected for the third time last May, according to Reuters. The FDA indicated that, at that time, Endo needed to provide an improved plan to manage risks associated with the long-acting testosterone treatment. Aveed contains both testosterone and castor oil and the agency was concerned about the risks of castor oil
leading to pulmonary blood vessel blockages and complications associated with post-injection reactions.

Current testosterone treatments include skin patches; short-acting injections; topical gels; and the buccal system, which involves application to the upper gum or inner cheek. Products include AbbVie Incs AndroGel, Androderm, Axiron, Bio-T-Gel, and Delatestyl. Endo International, previously known as Endo Health Solutions Inc., announced that its Aveed will be launching early this month, Reuters reported.

Meanwhile, the FDA recently issued a Drug Safety Communication in which it announced its investigation of increased stroke, heart attack, and death risks in men taking currently FDA-approved testosterone products, such as Androgel. The agency also indicated that it is monitoring cardiac and death risks tied to testosterone products for approved uses and is re-assessing these risks following the publication of two separate research studies on the matter. Both studies suggest that an increased risk of cardiovascular events was seen in men prescribed and receiving testosterone therapy.

Public Citizen, a consumer advocacy group, has urged the FDA to increase the warnings about these risks on drugs labels, calling for the agency to add a Black Box warning, the FDAs most serious warning, a prior Reuters report stated. According to the FDA, no approved testosterone product has been cleared for use in men diagnosed with low testosterone that is not linked to a medical condition. Medical conditions include the genetic failure of the testicles to produce testosterone, according to a previous Reuters report.

The first of the two studies was published in the Journal of the American Medical Association (JAMA) last November, and involved older men. The research suggested increased risks for stroke, heart attack, and death were seen in men prescribed testosterone therapy. The second study, published in journal, PLoS, also suggested increased risks for heart attack in older men, and in younger men diagnosed with a pre-existing heart disease.

Low-T drugs have been tied to a number of significant side effects, including pulmonary embolism, deep vein thrombosis (DVT), stroke, heart attack and other cardiovascular injuries, and death. In fact, since the FDAs announcement, four AndroGel lawsuits were filed in U.S. District Court, Northern District of Illinois. All of these lawsuits similarly allege that the use of AndroGel caused the men, all of who allege no prior history of cardiac disease, to suffer heart attacks, heart failure and stroke.

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Federal Regulators Investigating Cardiac Risks for Products Approved for the Treatment of Low Testosterone in Men …

February 28, 2014

http://www.testosterone.me/tag/public-citizen
Public Citizen indicated that its petition was based on mounting evidence pointing to cardiac risks indicated in studies since 2010, as well as a recent published analysis of 27 studies that went back at least two decades, the Reuters report indicated. The advocacy group also indicated that of 27 studies, the 14 that were not industry funded revealed what it described as a highly significant increased risk for cardiac injury.

Low-T drugs have been associated with serious side effects that include pulmonary embolism, deep vein thrombosis (DVT), stroke, heart attack and other cardiovascular injuries, and death. Mounting research pointing to significant adverse reactions, the ongoing upward sales trend associated with these products, and mounting lawsuits that allege heart attacks following use of these FDA-approved Low-T medications (Case Nos: 1:14-cv-00776, 1:14-cv-00780, 1:14-cv-00777, and 1:14-cv-00772), have prompted Parker Waichman LLP to evaluate claims associated with these products.

Since the FDA announcement four AndroGel lawsuits were filed in U.S. District Court, Northern District of Illinois. All of the lawsuits similarly allege that the use of AndroGel caused the men bringing the lawsuit all allege no prior history of heart disease to suffer heart attacks, heart failure and stroke (Case Nos: 1:14-cv-00776, 1:14-cv-00780, 1:14-cv-00777, and 1:14-cv-00772).

If you or someone you know has taken a Low-T medication, you may have valuable legal rights. To discuss your case with one of our lawyers, please view our Testosterone lawsuit website or call 1-800-LAW-INFO (1-800-529-4636).

Contact: Parker Waichman LLP Gary Falkowitz, Managing Attorney
1+ (800) LAW-INFO 1+ (800) 529-4636 http://www.yourlawyer.com

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Federal Regulators Investigating Cardiac Risks for Products Approved for the Treatment of Low Testosterone in Men ...
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The rest is here: Testosterone Lawsuits Move Forward, as Bernstein Liebhard LLP Notes Push for Stronger Heart Attack Warnings on Low...

Testosterone Treatment Lawsuit News: Alonso Krangle LLP Commends Public Citizens Call for Heart Attack Warnings on ...

February 26, 2014

Alonso Krangle LLP, an experienced law firm investigating testosterone treatment lawsuits involving AndroGel and other prescription low testosterone, or Low T, therapies, commends the consumer advocacy group, Public Citizen, on its petition calling for new heart attack warnings on this class of medications. According to a statement issued by the firm on February 25, 2014, Public Citizen has petitioned the U.S. Food & Drug Administration (FDA) to immediately add black box warning the most serious type of safety notice, to the label of AndroGel and other Low T therapies in order to alert the public of their potential to cause heart attacks and other serious cardiovascular problems. [citizen.org/pressroom/pressroomredirect.cfm?ID=4092, February 25, 2014]

The Public Citizen petition follows the January 31, 2014 announcement by the FDA that it was launching a safety review of prescription testosterone therapies after two studies indicated they may raise the risk of heart attacks, strokes, and other serious heart problems in certain men. One of those studies was published in the Journal of the American Medical Association (JAMA) in November 2013, and suggested that older men with underlying heart disease faced a 30-percent increased risk of stroke, heart attack, and death if they were undergoing testosterone therapy. A second observational study cited in the FDA alert suggested a doubling of the risk of heart attack in older men, as well as in younger men with pre-existing heart disease, who underwent testosterone therapy. [fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm384225.htm, FDA, January 31, 2014]

Among other things, the Public Citizen petition points out that one analysis found that 14 of 27 studies published over the past 20 years linked prescription Low T therapies to highly significant increased cardiovascular risks. While the remaining 13 studies did not show a heightened risk of heart problems, all were funded by the pharmaceutical industry. [citizen.org/documents/2184.pdf, Public Citizen, February 25, 2014]

Since the FDA alert was issued, court documents indicate that at least four AndroGel lawsuits have been filed in U.S. District Court, Northern District of Illinois in on behalf of plaintiffs who allegedly suffered heart attacks, heart failure and strokes, due to their use of the drug. All of these lawsuits raise questions regarding the marketing tactics used to drive sales of prescription testosterone treatments. Among other things, the complaints allege that aggressive direct-to-consumer advertising caused many men to seek out treatment, and to be prescribed these medications, even though they were not suffering from low testosterone levels. (Case Nos: 1:14-cv-00776, 1:14-cv-00780, 1:14-cv-00777, and 1:14-cv-00772)

In light of these developments, the testosterone treatment lawyers at Alonso Krangle LLC agree with Public Citizen that new warnings alerting patients and doctors to the potential heart risks associated with these medications are urgently needed. The Firm calls on the FDA to act as soon as possible in order to mitigate this serious public health threat.

The attorneys of Alonso Krangle LLP are offering free testosterone therapy lawsuit reviews to men who may have suffered serious heart problems due to AndroGel or a similar medication. To learn more, please contact one of the experienced consumer injury lawyers at Alonso Krangle LLP by calling 1-800-403-6191 or visit our website, http://www.FightForVictims.com.

About Alonso Krangle LLP Andres Alonso and David Krangle, attorneys with almost 40 years of collective legal experience, have focused their law practice on the handling of significant personal injury cases, defective drug and medical device litigation, construction site accidents, nursing home abuse, medical negligence, qui tam whistleblower actions and consumer fraud cases. A nationwide law firm representing injured victims throughout the U.S., Alonso Krangle LLP is headquartered in Long Island, New York, with offices in New York City, and New Jersey. To discuss filing a testosterone therapy lawsuit, please contact Alonso Krangle LLP at 1-800-403-6191 or visit our website, http://www.FightForVictims.com.
Drugs to treat low testosterone should carry strong label warnings about the risk of heart attacks and other cardiovascular problems, the consumer advocacy group Public Citizen urges.

Public Citizen petitioned the Food and Drug Administration (FDA) to add its strongest possible warning a black box warning to labels on testosterone drugs, Reuters reports. The FDA approved testosterone therapy for men who lack testosterone or have low testosterone in conjunction with an associated medical condition, for example, genetic failure of the testicles to produce testosterone. Loss of libido, depression, decreased muscle mass and fatigue are among the symptoms of low testosterone, but Public Citizen says that nearly 25 percent of men who are prescribed testosterone have not had a blood test to determine if their level is actually low.

Public Citizens petition is based on evidence of the risks of heart attacks and other cardiac problems from studies dating to 2010 and from a recent analysis of 27 studies that go back as far as 20 years. Public Citizen says the 27 studies in the analysis diverge on the question of cardiovascular risk. The 14 studies not funded by the pharmaceutical industry showed a highly significant increased risk, while the 13 funded by drug companies showed no increased cardiovascular risk, according to Reuters. In January, the FDA issued a safety alert saying it would reassess this safety issue based on the recent publication of two separate studies that each suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy.

The FDA alert said the agency had not concluded that testosterone does, in fact, increase heart problems. Dr. Sidney Wolfe, senior adviser to Public Citizens health group, calls this statement reckless. It is quite clear that testosterone treatment increases the risks of cardiovascular diseases, including heart attacks, Wolfe says. The FDA issued the alert after PLoS ONE published a study showing that men over 65 had a two-fold increase in the risk of heart attack within 90 days of filling a testosterone prescription. Men under 65 with a history of heart disease showed a two- to threefold increased risk of heart attack; no increased risk was reported for younger men without a history of heart disease, according to Reuters. The increased risk for older men occurred regardless of whether they had a previous history of heart disease.

See the article here:
Consumer Group Urges Cardiac Risk Warnings on Labels of Testosterone Drugs

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