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Advocacy Group Files Lawsuit Seeking FDA Action on Propecia

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A new lawsuit filed against the FDA this week contends that the male pattern baldness drug Propecia (1 mg) should either be taken off the market or its prescribing information should include warnings about the risk of long-term erectile dysfunction, depression and suicide.

The consumer watchdog group Public Citizen filed the suit Sept. 8 in the U.S. District Court for the District of Columbia on behalf of the Post-Finasteride Syndrome Foundation (PFSF). The complaint asks the FDA to act on a petition the foundation filed in 2017, which has gone unanswered.

The case has more merit than it did when originally filed, Philip Roberts, PFSF's patient manager, told
FDAnews
. "Much more scientific information has come to light since then," he said, including two studies by Harvard investigators confirming the risk of long-term erectile dysfunction, depression, suicidal ideation and suicide; and epidemiologic data showing that the drug alters the expression of more than 3,700 genes in men who take the drug. The drug mimics a male hermaphroditism gene; people who have this are genetic males who sometimes look female and who never go bald.

The 2017 petition asked FDA to either withdraw 1 mg oral Propecia from the market or include a Black Box warning and send out a "Dear Healthcare Provider" letter, alerting clinicians to the risks associated with the medication. The petition included information on about a dozen men whose suicides were considered related to Propecia use and contraindications for patients with a history of sexual dysfunction and depression.

Since then, PFSF has amassed more data, including 17,953 adverse event reports filed in the International Drug Monitoring database. These include reports of erectile and sexual dysfunction (5,234) and 4,313 reports of psychiatric disorders, including anxiety (1,756) and depression (1,386). The database includes 88 cases of completed suicides, 39 attempts and 384 cases of suicidal ideation.

In light of Propecia's enormous global market (almost 9 million users in 2018, according to the website ClinCalc.com), the numbers are very small. Nevertheless, they represent an unnecessary tragedy that needs to be addressed, said Michael Kilpatrick, the Public Citizen attorney who filed the suit.

“It’s a small percentage, but the number of prescriptions is so high that it’s still a large number of people,” he told FDAnews. “We think patients should know this. It’s a drug for a cosmetic issue. If people knew there was even a slight change you could develop a significant, life-altering syndrome and even think about suicide, they might not want to take it.”

The FDA has been sitting on the matter far too long, he said.

“A four-year wait is unreasonable. Our goal is to compel FDA to issue a decision on the original petition. We think it’s a strong one and that the decision should be for granting a black box warning or even withdrawing the drug. This delay is in violation of the Administrative Procedure Act and given the seriousness of the issue and the quality of the petition, it should be resolved.”

Merck didn’t reply to a request for comment. The company has moved all of its Propecia patient and prescribing data to a new company spinoff, Organon, launched on June 3.

Read the PFSF complaint here: www.fdanews.com/09-09-21-Complaint.pdf (https://www.fdanews.com/09-09-21-Complaint.pdf). — Michele G. Sullivan