

**Welt am Sonntag**

March 19, 2017

## **For Risks and Side Effects, Ask Donald Trump**

**Finasteride is considered a miracle cure for hair loss, but patients report serious side effects—and now want to sue**

**By Anette Dowideit**

Alex Johnsson\* lives entirely within a 300-square-foot space: his furnished, rented apartment in West Berlin. His life was meant to be much different, working for a corporate law firm in New York, closing deals with major companies, residing in a deluxe abode.

The fact that this 34-year-old man instead sits in his flat all day, barely moving, barely sleeping and wholly unable to work, is the direct result, he says, of a prescription medication he took 18 months ago. To be precise, just 16 finasteride pills.

The hair-loss drug has achieved worldwide success. Market-research firm IMS Health estimates that its manufacturers have sold 16 million Euros worth of finasteride in Germany alone, and an additional 5 million in Internet sales, according to Gerd Glaeske, a pharmaceutical analyst from Bremen.

The drug, which has recently fallen into disrepute, is even used by Donald Trump, according to one of his doctors. As reported in a U.S. study, it causes permanent erectile dysfunction, and that is just the beginning of more serious health concerns. Depression and inability to concentrate are some of the side effects that some patients experience.

How did the authorities fail to protect the public from such a danger?

The prescription medication, which is an effective dermatological therapy for male hair loss, was initially developed for prostatic enlargement. Finasteride affects the hormonal balance, reducing the conversion of testosterone to dihydrotestosterone (DHT), and slowing down the hair-loss process.

Finasteride was originally distributed by U.S. pharmaceutical company Merck (MSD in Germany). But at present, generic drug manufacturers are profiting the most from the drug.

In the U.S., finasteride has been controversial for several years now, with more than 1,400 men filing lawsuits against Merck, citing irreversible damages, such as difficulty concentrating, depression, muscle wasting and sexual dysfunction. The media in Great Britain, France and several other countries have raised concerns about the drug. If these accusations are founded, taking finasteride is like playing Russian roulette: it can either go well or very wrong; so wrong that the patient's life will never be the same.

The Post-Finasteride Syndrome Foundation, a U.S.-based organization, is fighting for the rights of the patients negatively impacted by finasteride. They have made it their mission to inform the public of the drug's risks. The 22-year-old son of founder John Santmann took his life in 2008, due to severe depression that his family believes was caused by the medication.

On PropeciaHelp, a community of people harmed by the drug has grown steadily; they chiefly discuss the different side effects they endure, such as muscle wasting, digestive ailments, skin irritations, and the list goes on. They refer to these symptoms as post-finasteride syndrom (PFS), and they believe the condition is not curable.

It is very hard to prove that such disorders are caused by finasteride. While some men have shown side effects right from the beginning, others developed symptoms months after they stopped taking the drug, so it is possible that many men suffer from depression, impotence and inability to hold down a job without even knowing that their condition may be linked to the hair-growth remedy they took years ago.

Research on the long-term effects of the drug is almost nonexistent. New studies from scientists at Northwestern University, funded by the PFS Foundation, are among the few such studies on the topic. According to these studies, on average, one out of every 100 finasteride users suffers from persistent erectile dysfunction.

Many doctors in Germany are convinced that finasteride can be harmful to the body. One of them is the Prevention physician Uwe Höller. In his doctor's office in Bergisch Gladbach in Köln, he has been treating many men who suffered heavy side effects after taking the substance.

One of his patients who suffered severe depression had to spend four months in a psychiatric clinic, yet to no avail.

Höller has a pile of medical records from different patients on his desk.

"Although the side effects of each might differ, all patients have one similar abnormality," he says. Based on several markers, it can be proven that all the affected patients he has examined have a sustained damage of the Mitochondria, cell components that are responsible for basic metabolic processes in the body.

If the components of the cells are not fulfilling their tasks, it is logical that the body will respond in odd ways. In an interview with Welt am Sonntag, five men have described their common symptoms. All of them suffer from sexual disorders, and they can barely concentrate, so keeping a job is almost impossible. This would mean that the effects of finasteride are even more damaging, because the drug destroys both the work and social lives of the patients. For most, no standard treatment can help, says Dr. Höller.

In the summer of 2014, Alex Johnsson got the medication prescribed by his doctor. Only a few days later, he noticed the first side effect: mood swings.

"I felt dazed," says Alex. Around two weeks later, he quit the drug. Three months later, while taking a walk, his penis became numb. Erectile problems occurred, as well as loss of sexual desire.

He was in New York City on business at that point. But very soon, he had to return because he was having panic attacks, couldn't sleep anymore, and suffered depression.

Johnsson found shelter at his parents' house. He sought help from doctors, psychotherapists, and healing practitioners, yet with no success. Nobody believed his symptoms might have been caused by finasteride. In the meantime, he found the PFS-Forum, where many others complained about the same ailments.

He acknowledges that theoretically, it could be all coincidental, or that perhaps, after reading the symptoms in the forum, these people just believe they suffer from the same thing. But that doesn't explain the changed biomarkers results. What's more, no doctor has offered a different diagnosis, such as muscular dystrophy.

Today, Johnsson is unfit to work. He says that his inability to concentrate is a major issue, and he is not able to read long passages and understand the context. He also suffers from

terrible muscle aches, which makes walking very hard. Together, with a teacher from southern Germany who was also affected, he started a lawsuit. They are suing a company that produces generic finasteride, Dermapharm, and the government supervisory authority, the Federal Institute for Pharmaceuticals and Medical Products (BfArM), which is responsible for consumer protection.

Johnssons' lawyer, Jörg Heynemann, a medical-malpractice attorney from Berlin, is demanding that both the manufacturer and the supervisory authority declare how much they knew about the heavy side effects.

They have not fulfilled their obligation, and that is the reason we are suing, says Heynemann. He wants to find out if the authority could have done something to warn the patients of the heavy risks, requesting the manufacturer to point out or declare a distinct possibility of permanent health impairment. To this day, they only warn of unspecified erectile problems. This results in some doctors prescribing the medicament carelessly. Johnsson says he got the prescription in five minutes.

Dermapharm did not respond to any questions, unlike the BfArM, which is more open. They declared that, thus far, there are 17 cases where it's suspected that finasteride has caused depression, and 28 cases of erectile dysfunction. In total, there are 170 reported cases of unwanted side effects. This has prompted them to list depression as a side effect on the product's label.

An official recognition of the side effects would bring legal consequences, leading to more patient complaints of damage. For finasteride, this could result in a halt in production. The whole case could influence doctors to be more reserved when prescribing such drugs, and patients to be more careful.

\*Not his real name.