Die Welt May 22, 2019

Editor's note: This English translation was done by a third party. The original digital report can be accessed <u>here</u>.

Hair-loss Trial: Plaintiff Seeks Compensation

A bald head caused by hair loss can be a big issue, and pills containing finasteride can help. However, the price one has to pay is enormous: it will cost you your health. One victim has sued the pharmaceutical manufacturer. Is this case a precedent?

(Paderborn, Deutsche Presse-Agentur) "I took a hair-loss pill and paid the ultimate price—with my health." This is how a victim of the hair loss medication describes his situation. Now he is demanding 100,000 euros from the pharmaceutical manufacturer as compensation.

The trial started on Wednesday at the District Court in Paderborn. At the hearing, the man, who is from North Rhine-Westphalia, stated that he has been suffering from severe side effects for years, what's known as "post-finasteride syndrome."

The case has caused a stir because the active ingredient in this hair-loss medication is finasteride, which is prescribed thousands of times in Germany—prompting many reports of health problems. The pills caused the claimant serious side effects, says Stephan Bensalah of Roland ProzessFinanz AG, the law firm handling this "model case."

The victim, a business-school graduate, is a man in his mid-thirties and prefers to keep his name private. After taking the medicine for four years, he suffers from depression, suicidal thoughts, sexual problems (such as erectile dysfunction), fatigue, concentration and memory disorders.

The claimant is unable to have a normal career, Bensalah tells DPA.

The defendant argued that the claimant's health complaints were not caused by the stated medicine and that the reported "adverse events" are always recorded, analyzed and communicated to the appropriate authorities.

The active substance can be found in several prescribed medicines and is being used for the treatment of androgenic alopecia, or benign prostate enlargement. Since the health insurance companies usually do not cover the costs of the drug, it is difficult to quantify how often it is sold, but it is a very common drug.

According to expert Uwe Höller, finasteride is the most prescribed drug in Germany against hair loss and it is sold thousands of times every year through German pharmacies. The physician from Bergisch Gladbach treats patients with post-finasteride syndrome, especially men with mental disorders. Höller is of the opinion that finasteride should no longer be prescribed for hair loss.

According to the Federal Institute for Drugs and Medical Devices (BfArM), the efficiency of finasteride for patients with androgenic alopecia has been proven. The benefit-risk ratio of finasteride is considered as positive, and therefore it is authorized for sale. This benefit-risk balance is constantly monitored on a European level and rated positively, explains a BfArM spokeswoman. But side effects such as depression and sexual dysfunction have been proven in studies and these effects continued even after discontinuation of the therapy "months to years" on. Individual case reports show that some side effects have lasted longer than 10 years.

Physicians were warned in the summer of 2018 in a "Red Hand Letter" about the risks of finasteride containing medicines by license holders and manufacturers in cooperation with the BfArM. The following risks were mentioned: sexual dysfunction and decreased libido, as well as depression with suicidal thoughts. According to Roland ProzessFinanz, there are many victims. Another "model lawsuit" is going on in Berlin, and a third one is planned for October in Stuttgart.

On the first day of the trial in Paderborn, the plaintiff was met with partial success: The defending pharmaceutical companies must hand over detailed information on effects, interactions, side effects, and information about all known suspected cases, according to a court spokesman.

There are eight other participants supporting the three plaintiffs who will go to court as well, says Bensalah. One of them is Thomas M., 36, from North Rhine-Westphalia. "I'm almost impotent and I have severe pain in the abdomen, which ranges from unpleasant to unbearable," he says.

Thomas can't sleep, because the medicine attacked his hormone balance, and has extinguished his sexual desire. This healthy, active and positive person has become an overweight, pain-stricken man with depression, even though he discontinued the drug at the end of 2015. He has no other choice than to bury his desire to become a father.

But above all, Thomas wants to achieve one thing: "My goal is to make finasteride disappear from the market."