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When Fighting Hair Loss, Watch out for Finasteride

PHARMACOVIGILANCE: Diminished libido, depression, suicidal ideation...taking this drug that slows hair loss can lead to serious adverse effects. An association is calling for it to be pulled off the market.

By Pascale Santi

Editor's note: This English translation was done by a third party. The original report can be accessed at Le Monde online.

Romain Mathieu killed himself on June 7, 2016. He was 25 years old and suffering from depression. At just 19, while a student doing advanced college-prep work, he began taking Propecia (finasteride), a medication that slows hair loss in men. He took it for two and a half years. Shortly after starting on the drug, he began experiencing sexual issues (loss of libido, ejaculation problems), extreme fatigue and difficulty concentrating. So he began a long series of medical consultations and tests, none of which helped or brought him relief... After Romain's death, his mother, Sylviane Millon-Mathieu, created an association called Helping Victims of Finasteride ([French acronym] AVFIN).

Among those victims of finasteride is Adrien (a pseudonym): "He lost everything," says his father, "his work, his life as one half of a couple, his vitality..." He is currently 32 years old and only took the medication for a few months. But he experienced adverse effects quickly: loss of libido, trouble concentrating, fatigue... These side effects got worse over the years, even after he stopped treatment. He currently suffers from severe depression. As in the case of Romain, he and his family strongly suspect this is due to finasteride, a connection he discovered too late. Medical authorities claim that it is not possible to link these symptoms with absolute certainty; that other causes are possible.

Available in France since 1999, as well as elsewhere in Europe, Propecia and its generic versions are prescribed to treat hair loss in men (andro-genetic alopecia), which leads to baldness. Millions of men have taken it, or are taking it, since its introduction to the market. In 2012, the National Agency for the Security of Medications and Health Products ([French acronym] ANSM) claimed that 30,000 boxes of finasteride per month were used, a number that is now declining.

The license to market finasteride, a product that lowers testosterone levels, was first issued in 1992 (for a 5mg dose) for benign prostate enlargement. "There was a movement in the prescription process to off-label use of the product – different from its initial use," affirms Professor Jacques Young, an endocrinologist at Bicêtre Hospital [in Paris], who has never prescribed it for alopecia. "The evidence of its efficacy in clinical trials was too weak for what was basically cosmetic use." It is not reimbursed by French Social Security and is dispensed only with a doctor's prescription. It is forbidden for use by women.

"Certain people cannot deal with losing their hair," explains Professor Jean-Luc Schmutz, head

of the dermatology unit at the [Centre Hospitalier Régional Universitaire] of Nancy-Brabois. "There are only two treatments, Minoxidil, a topical lotion that doesn't work very well, and Propecia, which makes hair grow, or stops hair loss, in 30% to 40% of cases. I still sometimes prescribe it, without serious side effects." He has, however, noticed libido problems in certain patients, which dissipate when they stop taking the medication. "It must be prescribed with precautions and awareness of the reported adverse effects," he said, "warning patients and seeing them regularly."

In May 2016, the magazine Prescrire warned of "important adverse effects," basing its comments on a 2015 alert from the [Canadian Agency for Drugs and Technologies in Health]. In 2017, the European Medicines Agency asked that a mention of mood changes be added to the product inserts. Then an alert was issued by ANSM at the end of October 2017, mentioning risks of depression, suicidal ideation and the possible persistence of sexual problems such as the loss of libido. "Any mood shift should be addressed by stopping the treatment and/or watching the patient," said ANSM. The agency will, in the next few weeks, send a letter to 100,000 health professionals to remind them of these adverse effects.

And there is another reported adverse effect, the occurrence of male breast cancer. A study of 45,000 people in Northern European countries has nearly been completed. "Preliminary results are somewhat reassuring," says Doctor Caroline Semaille, from ANSM's Anti-Infectious Medication Department. "In general, adverse effects are rather rare." In total, since being introduced to the market, 345 cases have been reported to the French pharmacovigilance service, says ANSM, which reminds us that patients are supposed to notify them. The MSD laboratory (a branch of the American company Merck, which sells Propecia), says, "We have not seen any particular alerts about adverse effects."

Targeted Aesthetics

But for AVFIN, after learning of these debilitating adverse effects, such warnings are not sufficient. The association is asking that the medication be pulled from the market. "The risk-benefit relationship is different for this medication, because it's only prescribed for aesthetic reasons, for men in otherwise good health," explains Sylvaine Millon-Mathieu. For ANSM, this is not an issue: the drug has not been pulled anywhere in the world.

"The risk- benefit balance is for the moment considered to be favorable," adds Caroline Semaille. But Prescrire advised, in September 2018, "If you have hair loss, it is not a good idea to take finasteride."

Members of AVFIN emphasize that none of their doctors ever warned them about adverse effects. "A young engineer and a strong athlete, Adrien was reluctant to take the medication, and he specifically asked his doctor if he could take it without risk," says his father. "Sexual, psychological and physical side effects persist almost systematically when the treatment is stopped," declares Sylvaine Millon-Mathieu.

In the United States, Canada, Germany and Italy, legal actions are ongoing. Attorney Charles Joseph-Oudin, known for having worked with victims of the drugs Mediator and Dépakine, will

be suing the MSD Laboratory in the next few days, at the [District Court] in Nanterre. He is currently advising some 30 people. He is asking for "appraisals to be done to establish causality between Propecia and certain adverse effects, such as major depressive disorder and a loss of vital energy." To do this, he says, "we are asking for the implementation of centralized studies at the level of the National Office for the Indemnification of Medical Accidents, which may substitute for judicial experts who don't work as well." Currently for the association, it is essential that someone be fully in charge medically of the victims.

"Doctors and pharmacists must inform patients about medications, but the patients must take charge of their own health, looking not just at social media, but also reading the product inserts and searching public databases for information about medications," advises Caroline Semaille.

Donald Trump: Official Propecia User

The President of the United States, whose orange-tinted coiffure attracts a lot of commentary, takes finasteride. His former doctor, Harold Bornstein, let this information slip in early 2017 in The New York Times. And the medical report published January 16, 2018 on the American president's health by his then-doctor Ronny Jackson confirmed that he currently takes finasteride 1mg, which caused some concern on the other side of the Atlantic. In May 2017 an article in JAMA Internal Medicine magazine studying men aged 66 and older revealed that the medication "raised considerably" the risk of self-mutilation and depression. Donald Trump is 72 years old.