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The Victims of a Hair-loss Treatment Are Suing MSD

Propecia, a medication made from finasteride and used to fight male hair loss, also causes depression and sexual problems. According to our information, for the first time, three French men have filed suit against the MSD Laborary, while 30,000 French men continue to take the drug—and several associations blame the drug for dozens of suicides worldwide. The hearings is set to begin June 4

by Rozenn Le Saint

For the first time in France, three Propecia victims are suing American pharmacuetical giant Merck Sharp & Dohme (MSD). They are filing their suit against the maker of this hair-loss medication in the High Court of Nanterre, claiming a lack of information about its expected benefits (purely cosmetic), and the risks involved when taking it, which they claim are extremely serious. This past Tuesday, the hearing was scheduled for June 4.

Jérémy is planning to join their judicial quest. In November 2017, he nearly threw himself out a window, a few days after taking Propecia (the finasteride treatment produced by MSD) for the first time. Back then, Jérémy enjoyed swimming at a pool five times a week. His face, wearing his tight swim cap, pleased him, and he was absolutely not balding – his temples and his head were thinning just a little in the back. He was far from being the wreck he says he has become.

Jérémy was 31 at the time, working as a nurse. "I consulted a dermatologist on a preventative basis," he says. "He presented Propecia to me as *the* miracle drug against hair loss." According to clinical studies run by the lab, its benefits were not particularly stellar: the medication only works in 40% of cases. And its effectiveness is quite limited: at its best it will increase hair growth by 10%. And only on the top of the head, not on the temples. And – importantly – it only lasts as long as the treatment is continued.

Jérémy read the product insert and was somewhat taken aback by the list of potential adverse side effects, notably the sexual problems. But these side effects were described as "infrequent": 1% of cases, maximum. "I said to myself, 'Why should this happen to me?' and I decided to take it. I would never ever have taken it if I'd been aware of one-onehundreth of the side effects I'm still experiencing," he says.

If the image of Mr. Clean (a bald, smiling man) embodies the concept of pure virility, there's a reason why.

The higher the testosterone level is in men, the more they will eventually lose their hair. Finasteride, which is Propecia, lowers testosterone, which slows hair loss. Except that a drop in this male hormone also affects the libido, and can trigger excessive development in the chest area, including breast cancer, as well as cause depression and even suicidal ideation. Donald Trump, the American president, takes finasteride.

In the United States people are worried that the leader of their nation is taking finasteride. Apparently the risk of depression is higher for those older than 66 who want to preserve their hair at any price. and Trump is currently 72.

After taking a total of jsut two half-pills, Jérémy experienced terrible, intense fatigue, and his sexual life was destroyed. No more early morning erections; weird, retrograde ejaculations; failure when trying to have sex; then no more erections at all. He went on sick leave for five months, took antidepressants, had daily testosterone shots injected directly into his penis – which he is still doing – and was dealing with a relationship that was breaking up.

His girlfriend is a pharmacist. In her files, she found that often after patients begin taking finasteride, they return with a scrip for anti-depressants. Jérémy made the connection.

He reported his case to the French pharmacovigilance database, like 290 other victims of this drug treatment. Then he went to see the Dante law firm in Paris, encouraged by the association Aid to the victims of finasteride (AVFIN).

A lack of information and the 'defectiveness' of a medication

Charles Joseph-Oudin is applying for summary judgment against the giant American firm at the High Court in Nanterre. It is the first suit of this kind in France, whereas complaints have already been filed in the United States, Canada and Germany. He has chosen a civil suit to claim the "defectiveness" of the medication, as he did with Servier for the victims of Mediator.

He goal? To get the court to require urgent expert opinion, prerequisites for any demands for compensation. "We'll show the causality connection between Propecia and its adverse effects, prove that the victims were not sufficiently informed, when MSD was fully aware of the gravity of these risks, including when treatment was stopped," says the attornery who has become the principal French thorn in the side of pharmaceutical companies.

Joseph-Oudin may invoke "a favorable precedent when medications are used for aesthetic reasons" and a judgment of the Appeals Court on September 26, 2018. The highest court confirmed that a laboratory may be held responsible for having sold a product too dangerous when considering its possible benefits, even if the product insert does mention potential side effects.

Finasteride first appeared in French pharmacies in 1993, under the name of Chibro-Proscar, as a treatment for prostate problems. But six years later, a clever recycling of the product allowed the lab to push back by several years the patent which protected it from the arrival of generic versions. Now also listed as Propecia, finasteride would serve henceforth as a treatment for hair loss in men, offering a second, lucrative life to this medication marketed by MSD, one of the five largest pharmaceutical companies in the world.

Since MSD did not ask French Social Security to reimburse the cost of Propecia, the company was then free to set its own price. So a one-month treatment cost about 80 euros. Now that the American laboratory no longer has a monopoly on the drug, its price has dropped to about 60 euros, while generic versions cost between 15 and 30 euros.

In 2009, ten years after its arrival on the French market, MSD finally mentioned in the product insert the risks of sexual problems "persisting after stopping the treatment."

But it was not until April 2017 that the European Medicines Agency (EMA) recommended the replacement of the words “depressed mood” by “depression,” and the addition of the words “suicial ideation” to the list of side effects, as requested by the French Agency for the Safety of Medication (ANSM). That agency relayed these changes to French patients and doctors in a communiqué sent on October 26, 2017.

The medication agency could forbid dermatologists to prescribe it

Considering these risks, why does ANSM not prohibit in France the use of this hair-loss medication? “It’s up to the health authorities to remove medications whose side effects are disproportionate compared to their effectiveness. This would help everyone make decisions, doctors and patients,” says Bruno Toussaint, the editorial director of the independent medical magazine Prescrire.

But the “police” of French medications is hiding behind the position taken by the EMA, which has not taken this step on the European level. Neither the MSD Laboratory, the EMA, nor the French Ministry of Health, which were contacted multiple times, have responded to requests for interviews from Mediapart.

Yet ANSM is not without power in France. It could circumvent the European “obstacle” by advising the use of finasteride only for cases involving prostate treatment, and by authorizing only urologists to prescribe it. “Patients might then order it online for hair loss, without a prescription, and this would be dangerous,” says ANSM’s press office.

That, of course, is already possible. Jérémy tried it for himself after he was able to order finasteride without a prescripiton from a pharmacy website. On November 23, 2018, he reported this fact to the Order of Pharmacists, who punished the offending pharmacy by forbidding it to sell products…for a total of 15 days.

Preventing dermatologists from prescribing finasteride might also avoid other missteps: the drug is sometimes also prescribed off-label to treat acne, without either authorization or testing. Indeed, it was to treat a few pimples that Romain Mathieu was offered this hormonal treatment, at the age of 19. Sadly he took his life on June 7, 2016.

He was first concerned by a loss of libido, then severe depressive disorder. For him and his family, the cause was finasteride. “Before he committed suicide that June 7, Romain left me a note telling me, ‘If you have the courage, fight,’” says his mother, Sylviane Million-Mathieu, president of the association Aid to the Victimes of Finasteride.

Since then, she has been doing exactly that. Against MSD with Charles Joseph-Oudin, but also against the inertia of the world of white medical coats, which is closely connected to the pharmaceutical industry.

Sylviane Million-Mathieu is hardly the first person to have made this connection. In 2004, when Marc, 47, was prescribed Propecia, he was told that no matter what side effects he experienced, they would all disappear as soon as he stopped treatment. Five years after he quit the drug, he is barely surviving with the help of two crutches: an anti-depressant and a testosterone gel. He is one of the first 3 plaintiffs in France to sue MSD. For this man who lives in the Rhône-Alpes region, his moral, physical and sexual decline happened after 10 years on the medication. In his personal life he became a bachelor again, stopped for six months, began again, but with difficulty.

According to him, stopping the “cure” set off a sort of “internal crash of hormones.” This is what the victims’ associations call post-finasteride syndrome: the body is fighting to re-establish its hormone balance after having been artificially propped up for the duration of the treatment. “I am especially worried about the future,” he says. “These side effects are a social ticking time bomb. And my hormone situation will not improve with age.”

At least 60 other dossiers with the word finasteride written on it are stacked in the offices of the Dante law firm. And there are many others which may soon be added to the pile: the drug is still being taken by around 30,000 French men today. Is this another health scandal that could have been avoided?

Relaying the dangers when facing off against the pharmaceutical lobbyists

After issuing warnings in 1999 about sexual problems, then in 2009 about depressions, Prescrire, which has predicted all the latest French medical scandals, has arrived at the definitive conclusion that “in the event of hair loss it is *not* reasonable to take finasteride.”

Especially since there is another treatment available, a topical lotion called minoxidil. According to Prescrire, it is a lot less dangerous. And about as (in)effective as finasteride.

Disturbing scientific results were published in 2015. So, hoping to open doctors’ eyes, Sylviane Million-Mathieu is making sure the most influential among them relay the dangers of the drug, so to slow down the counter on the website of the Post-Finasteride Syndrome Foundation, which currently shows 59 suicides worldwide, of which there was one in France: her son.

This courageous whistleblower is also going after the disinformation campaign run by the lobbyists of the pharmaceutical industry, which prefers not to mention the adverse side effects.

At the end of 2017, she had checked out the top hair clinic in France, the Sabouraud Health Center, whose website offers “paid clinical studies.” To attract patients, the clinic dangles the possibility of being paid to be a guinea pig: new products and consultations are offered free of charge by the manufacturer(s).

So in 1994, 5 years before it was commercially available in pharmacies, patients at the Sabouraud Center were able to preview and test Propecia® as part of one of the many studies (6) listed in the authorization dossier for introduction to the market, according to Pascal Reygagne, director of the Center.

Pascal Reygagne refuses to tell us how much the Center received from MSD to evaluate the effectiveness of Propecia as it waited to obtain the precious green light for commercialization. “It is extremely naïve to be offended that clinical studies of new medications are financed by the industry. They are verified afterward by the medication agencies,” he says. The clinical trials help to financially balance the Sabouraud Center. They represent 10 to 20 percent of our budget.”

Are these preferential links with MSD leading them, a few years later, to overlook the lack of published information on the dangers of the medication?

On September 18, 2018, most of the known adverse effects were not listed on the webpage “medical treatments for male pattern balding” of the Sabouraud Center. AVFIN was

understandly concerned. Two days later, the document, signed by Pascal Reygagne, was no longer accessible online.

Historically, its prescriptions were the first in France to specify finasteride as a hair-loss treatment. Before the warning issued by ANSM in the fall of 2017, it the drug prescribed 10 times a day. Now it is more like 5 or 6 tines a day: patients are much more cautious.

Reygagne is known as “Mr. Finasteride” in France, being an expert and also the spokesperson for the very influential French Society of Dermatology (SFD). The laboratories know that skin specialists trust the society. Its communications inform their prescriptions, making them the principal targets for lobbying from Big Pharma. Since 2013, the pharmaceutical companies have given 3.1 million euros to the SFD. MSD, the manufacturer of Propecia, is the second most generous, contributing more than 500,000 euros, or 100,000 euros per year. These figures were obtained by Mediapart thanks to the online tool *EurosForDocs*, which monitors links (financial or otherwise) to the pharmaceutical industry.

What does this tool do? It offers real transparency when examining the data in the government database Transparence Santé [Health Transparency[, which is difficult to use in its raw form. Laboratories are supposed to list all contracts and gifts made to health principals – ever since the Mediator scandal in which major conflicts of interest were revealed involving “deciders” and Servier, its manufacturer.

Back then, doctors were circumventing the prescribed usage for the anti-diabetic medication, prescribing it instead as an appetite suppressant, without re-evaluating the famous risk/benefit relationship and causing an estimated 500 to 1,500 deaths. That trial will get under way in the fall.