From: [redacted]
To: **Ord, Kathryn** <Kathryn.Ord@mhra.gov.uk>
Subject: RE: CSC46623. [redacted]
Date: 09.11.2021 10:29:02 (+01:00)

Yes of course, thank you

From: Ord, Kathryn < Kathryn.Ord@mhra.gov.uk>
Sent: 05 November 2021 16:21
To: Pharmacovigilanceservice < Pharmacovigilanceservice@mhra.gov.uk> ; [redacted] mhra.gov.uk>
Subject: RE: CSC46623. [redacted]

Hi [redacted]
I think sending a holding reply and re-setting the clock to 15 days from now is sensible. We've only just found out about this and need time to look at [redacted] query properly so we can address any new points [redacted] raised.

[redacted] know you are very busy so I can try to draft a reply for this – would you be happy to check it for accuracy?

Many thanks,

Kathryn

From: Pharmacovigilanceservice < Pharmacovigilanceservice@mhra.gov.uk >
Sent: 05 November 2021 10:59
To: Ord, Kathryn < Kathryn.Ord@mhra.gov.uk > ; [redacted]
Subject: RE: CSC46623. [redacted]

Hi [redacted]

Apologies for this. We first received this email via the CS team on 5 th October and as they had said the following it looks as though no further action was taken:

"We have responded to the enquirer to confirm we have received their email and have closed CSC 46623."

@Ord, Kathryn can this be allocated to someone else? Alternatively we can ask the CS team to send a holding response and allow ourselves 15 days from today to send out a response.

Kind regards,
[redacted]

From: [redacted]
Sent: 04 November 2021 17:59
To: Pharmacovigilanceservice < Pharmacovigilanceservice@mhra.gov.uk >
Cc: Ord, Kathryn < Kathryn.Ord@mhra.gov.uk >
Subject: RE: CSC46623. [redacted]

Hi [redacted]

I'm sorry but I will be unable to respond to this by the 8 th of November. I am absolutely inundated and the response will take a lot of time to generate.
Either it is allocated to someone else or it is made clear that I'm not in a position to respond to him for several weeks (whatever is the longest timeframe acceptable).Do we not usually get 15 days at least?

Best regards
[redacted]

From: Pharmacovigilanceservice < Pharmacovigilanceservice@mhra.gov.uk >
Sent: 04 November 2021 15:20
To: [redacted]
Subject: FW: CSC46623. [redacted]

Hi [redacted]

You have responded to this person's previous enquiries. Please can you help with this query?

Many thanks,
[redacted]

From: MHRA Customer Services < MHRACustomerServices@mhra.gov.uk >
Sent: 04 November 2021 12:59
To: Pharmacovigilanceservice < Pharmacovigilanceservice@mhra.gov.uk >
Cc: [redacted] >
Subject: FW: CSC46623. [redacted]

Dear PV Team,

The enquirer phoned today requesting an urgent response to his enquiry below. He asked if the response could be emailed asap by 8 November 2021.

Thanks for your help.

With regards

[redacted]
MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 0203 080 6000

gov.uk/mhra
Stay connected

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From: [redacted]
Sent: 29 September 2021 08:42
To: MHRA Customer Services < MHRACustomerServices@mhra.gov.uk >
Subject: CSC46623. [redacted]

Dear [redacted]

Thank you for your previous correspondence.

I wanted to add more to our conversation because since we last wrote more information has come to light.

Firstly, the PFS (Post Finasteride Syndrome) Foundation published a report which states:

1. Post Finasteride Syndrome Patients have been found to have an over/under expression of in excess of 3700 genes.
2. They compare the effect of Finasteride upon susceptible patients to castration.
3. They state the risk of suicide is so high that it can be referred to as a side effect.

I've attached the report to the foot of this email.

Next, Reuters published an article which stated

1. Merck deliberately witheld key data from medical trial results.
2. Merck were aware of elevated risk of suicide.
3. Merck settled out of court with PFS patients who pursued legal action.

[redacted]

I continue to be extremely concerned that Finasteride is being prescribed for cosmetic purposes, often with no real medical oversight.

Patients are not made aware of the full list of potential side effects or their severity when Finasteride is prescribed and cannot make an informed decision about the drug's safety profile. I had no idea that [redacted] was possible, let alone that it could be caused by a cosmetic treatment. The official advice from the manufacturer is that cessation of use will cause problems to abate, but the experience of PFS patients goes very much against this.

Those selling and manufacturing these drugs continue to be resistant to revealing the full extent of the side effects that can be inflicted upon a patient. Merck, owner of the Propecia (finasteride) brand, has been forced to repeatedly amend the side effect warning documents supplied with the drug and attempted to keep legal documents concerning Propecia's safety out of the public domain and as mentioned settled privately with those who took them to court. Their own safety testing omitted data from patients who became unwell.

People have no idea how serious a reaction to finasteride could be, how likely it is that they will have a bad reaction, how long they might expect to deal with side effects, etc. Aside from the symptoms themselves it is not explained that there are no treatments available for those affected, and that the mechanism by which these side effects are triggered isn't understood. Again, people cannot possibly know what they are risking based on information from manufacturers or from those who supply the drug, who recommend seeking help from doctors, despite doctors being completely unable to offer any treatment.

Marketing for Finasteride is becoming more prevalent, with online retailers offering prescriptions to patients who fill in a short questionnaire in lieu of real medical oversight. This advertising often targets young people and uses devices like celebrity endorsements to make the product more appealing. It makes me wonder if we will see an explosion in case numbers soon. I am fearful that many lives will be ruined or even lost after use of this drug. Though I am certain the drug will be reassessed with time, every day that passes sees more and more young men having their futures taken from them through use of a drug prescribed for cosmetic purposes. There are currently 18000 cases registered on Propecia Help alone. People complaining of a constellation of problems, including physical, sexual and neurological side effects with suicidal Ideation commonly reported.

As well as other patients the PFS Foundation have connected me with, I am aware of people in my social circle and local area who have been affected by use of Finasteride, [redacted]

I cannot possibly know definitively, but I am confident that embarrassment and stigma contribute to PFS patients not registering their symptoms with doctors and authorities.
Anecdotally, this would appear to be compounded by doctors who dismiss the symptoms and concerns of patients who do present when the symptoms don't match something better known or established. Despite the expectation that most general practitioners will have no idea about PFS, a growing number of medical professionals have begun to acknowledge the condition and are speaking out against finasteride.

The PFS Foundation has recently served the FDA with a lawsuit which demonstrates the seriousness of this.

I hope that this is beginning to convince you that this is a problem that needs more attention. I am happy to provide further information at your request or answer questions. I have attached the report from the PFS Foundation and the Reuters article can be found on line.

Yours Sincerely

[redacted]

From: Post Finasteride Syndrome Foundation [redacted]
Sent: Friday, 10 September 2021, 01:57
To: [redacted]
Subject: PFS Foundation Sues FDA for Unlawfully Failing to Grant or Deny Our Citizen Petition

[redacted]


Post-Finasteride Syndrome
FOUNDATION
Help Us Find a Cure
PFSFoundation.org

REGULATORY UPDATE

PFS Foundation Sues FDA for Unlawfully Failing to Grant or Deny Our Citizen Petition

Sept. 9, 2021

Dear Friends:

The Post-Finasteride Syndrome Foundation, represented by the consumer rights advocacy group Public Citizen , yesterday filed a lawsuit in Washington, DC, federal court compelling the US Food and Drug Administration to act on our Citizen Petition .

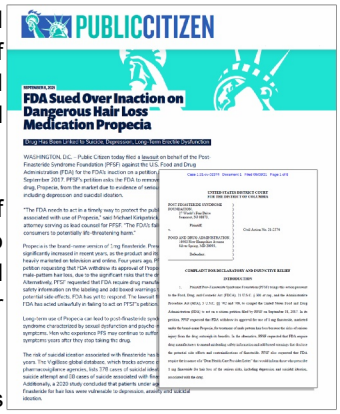
Facts laid out in the eight-page complaint include:

- The “most serious risk of 1 mg finasteride is suicide.”

- "A recent Baylor College of Medicine study showed significantly increased or decreased expression of more than 3,700 genes in men with PFS. Abnormal expression of genes can result in…adverse biological consequences."

- "Propecia's product labeling states that 'resolution [of sexual adverse reactions] occurs in men who discontinued therapy'… but in fact persistent sexual dysfunction…does not resolve for all men after discontinuing use of the drug."

- "Publications in 1990 and 1992 by…Merck's finasteride clinical development program… compared the effects of…finasteride to castration."


PUBLICCITIZEN

FDA Sued Over Inaction on Dangerous Hair Loss Medication Propecia

- "US prescriptions of 1 mg finasteride for hair loss more than doubled from 2015 to 2020. The most likely explanation for this dramatic increase is the emergence of telemedicine companies, such as Hims, Roman, and Keeps."

- The FDA has "unlawfully failed to either grant or deny" our citizen petition.

"The FDA needs to act in a timely way to protect the public from the risks associated with use of Propecia," **Michael Kirkpatrick** , the Public Citizen attorney serving as lead counsel, said in its announcement of the civil action. "The FDA's failure to act exposes consumers to potentially life-threatening harm."

"False information from the FDA leads physicians to dismiss patients, while some even tell them their symptoms are not real," added PFS Foundation CEO **John Santmann** , MD. "Without effective treatments for PFS, use of this cosmetic drug can lead to a lifetime of side effects. The drug ruins more lives every day and has no business being on the market."

Originally filed in September 2017, our petition is comprised of 120 pages of scientific and medical evidence that finasteride poses a threat to public health and should be taken off the market. Included therein are abstracts from eight thoroughly documented cases of PFS patients who took their own lives due to suffering wrought by the condition.

Among those cases is **Daniel Stewart** , a 37-year-old Professor of Criminal Justice at the University of North Texas who, in 2014, shortly after participating in our PFS clinical research at Baylor College of Medicine (BCM), hung himself at his home in Denton, Texas.

Also among those cases is a 42-year-old male "who developed psychoneurocognitive and sexual symptoms starting 2 years after initiation of treatment that never abated after discontinuation of finasteride… [yet had] no pre-existing sexual dysfunction, psychiatric or medical conditions prior to initiation of treatment… The Autopsy Report noted evidence of hanging by a belt... The brain and spinal cord were fixed in formalin prior to further examination and donated to medical researchers for studies currently underway."

That patient also participated in our PFS clinical research at BCM, which means that eight percent of all the patients in those studies committed suicide.

By December 2020, more than three years after we filed the petition, the FDA had not responded, yet a slew of new evidence had emerged to support our plea. So we filed two supplements:

Supplement 1 contained scientific research, epidemiological data and other pertinent information, including animal studies, clinical studies and label updates mandated in Europe by the European Medicines Agency, about anxiety and suicidal ideation, that the FDA has not implemented in the US.

Supplement 2 referred exclusively to the Reuters report headlined Court let Merck hide secrets about a popular drug's risks . Published in September 2019 after a yearlong investigation, the story uncovered testimony in the US Propecia litigation by former Merck executives suggesting that the pharmaceutical giant downplayed the drug's side effects during clinical trials. Specifically, Merck found evidence of persistent side effects in their original trials but failed to disclose such in their product label. Compounding this lack of

transparency, the judge in the litigation, **Brian Cogan** , inexplicably allowed Merck and plaintiffs' lawyers to keep information submitted in court under wraps.

Anyone living in the US who suffers from PFS should report his symptoms to the US Food and Drug Administration. Anyone living outside the US who suffers from PFS should report his/her symptoms to the US Food and Drug Administration and to his/her national drug-regulatory agency, as directed on our Report Your Side Effects page.

Finally, if you or a loved one are suffering from PFS, and feeling depressed or unstable, please don't hesitate to contact the PFS Foundation as soon as possible via our Patient Support hotline: social@pfsfoundation.org

Thank you.

Related News

Unsealed Documents from Propecia Litigation Now Housed on PFS Foundation Website (June 29, 2021)

PFS Foundation Files Supplements to FDA Citizen Petition Seeking Finasteride's Removal from the Market (Feb. 1, 2021)

Regulatory Update: France's FDA-Equivalent Issues Information Point and Fact Sheet on Finasteride Adverse Effects (Dec. 19, 2019)

Reuters Report on Merck Hiding 'Secrets' about Propecia's Risks Brings our FDA Citizen Petition to Light Ahead of Federal Probe (Sept. 16, 2019)

Regulatory Update: Canada Concludes 'There May Be a Link Between Finasteride and Risk of Suicidal Ideation' (Feb. 28, 2019)

Regulatory Update: France's FDA-Equivalent Agency Reissues Finasteride Warning (Feb. 2, 2019)

Regulatory Update: 'Muscle-related Disorders' Added to Canadian Finasteride Label in Response to Report by FDA-equivalent Agency (July 28, 2018)

Regulatory Update: Germany's FDA Equivalent Issues 'Red Hand Letter' on Finasteride ADRs (July 6, 2018)

Regulatory Update: European Medicines Agency Recommends Adding Depression and Suicidal Ideation to Finasteride Label (Aug. 10, 2017)

Regulatory Update: Korea Mandates Propecia Label Change Based on Reports of Depression and Suicidal Ideation (July 15, 2017)

Regulatory Update: MHRA Issues Drug Safety Update on Finasteride (May 26, 2017)

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