FDA Patient Listening Session on Post-Finasteride Syndrome

A Patient-Led Listening Session

June 2, 2023

Post-Finasteride Syndrome Network

About

Post-Finasteride Syndrome Network (PFS Network) is a patient-led registered charity[1] that advocates on behalf and advances the interests of patients suffering from the adverse reactions to finasteride currently known as post-finasteride syndrome, or PFS for short. Important actions of the charity include organizing and fundraising for scientific studies aimed at eventually uncovering a therapeutic and/or cure for the disease, hosting a podcast series that allows patients to raise awareness of the disease by sharing their lived experiences, and coordinating the volunteer efforts of patients and loved ones. Since its establishment in 2021, PFS Network has already organized two separate studies on the condition. The organization's web address is www.pfsnetwork.org.

PFS Network was the hosting organization for this patient listening session. The president of the charity, Mitch Sabine, gave the disease overview.

Background

What is Post-Finasteride Syndrome (PFS)

Post-finasteride syndrome is a rare condition that develops in a small subset of individuals exposed to finasteride or other inhibitors of the 5 alpha reductase type II enzyme. Disease onset can occur either during exposure or in the months following discontinuation. Symptoms commonly present across neurological, physical, and sexual domains. They persist indefinitely, and in many cases worsen after discontinuation. While the exact mechanism driving the disease is unclear, research has found an over-expressed androgen receptor in tandem with vast deregulation in the epigenome of post-finasteride syndrome patients, with affected gene clusters correlating with reported symptom areas. There is no cure or treatment for this condition, but patients often engage with therapists or counselors to work through coping with symptoms and life changes. For many patients, the disease is debilitating, and it often causes disability, isolation, and/or suicide.

Patient Listening Session

Context

Patient listening sessions are small, informal, non-regulatory, non-public discussions that allow participants to connect with FDA staff first-hand and share patient experiences, perspectives, and needs related to their health or a disease.
The objectives of this patient listening session were to:

[1] As of June 2023, PFS Network is a registered 501(c)3 organization in the United States and a registered charity in Australia. Everyone involved is a volunteer, and everyone involved is a patient.

1. Educate FDA regarding post-finasteride syndrome patients' symptoms, experiences, and needs.
2. Highlight the risks associated with finasteride exposure.
3. Share information regarding the post-finasteride syndrome community's wishes for effective treatments and/or a cure for this condition.
4. Inform FDA of the preferred treatment endpoints and of current and future research.

The meeting topics of this patient listening session included:

1. post-finasteride syndrome symptoms,
2. effects of the disease on quality of life,
3. patients' experiences within the healthcare system,
4. the lack of treatments for PFS symptoms and preferred treatment endpoints, and
5. the current research landscape and plans for future research.

Five patients and one caregiver/parent presented on their or their loved one's experience with the disease and its impacts.

Disease Overview

Introduction

The following video was shown as an introduction to the disease. It can be viewed here.

A Brief History

Persistent symptoms from finasteride exposure were first reported in 2003, with the creation of a support forum on Yahoo! Groups,[2] and have been occurring for two decades. Though awareness of the condition has grown within recent years, reports of the disease are largely contained within online patient communities. At the time of this patient listening session, there are nearly 10,000 registrations on patient support forums for the disease. The patient population has grown and continues to grow steadily.

The first research on the condition was published in 2011.[3] Scientific publications and concern from researchers and clinicians have increased in the years since.

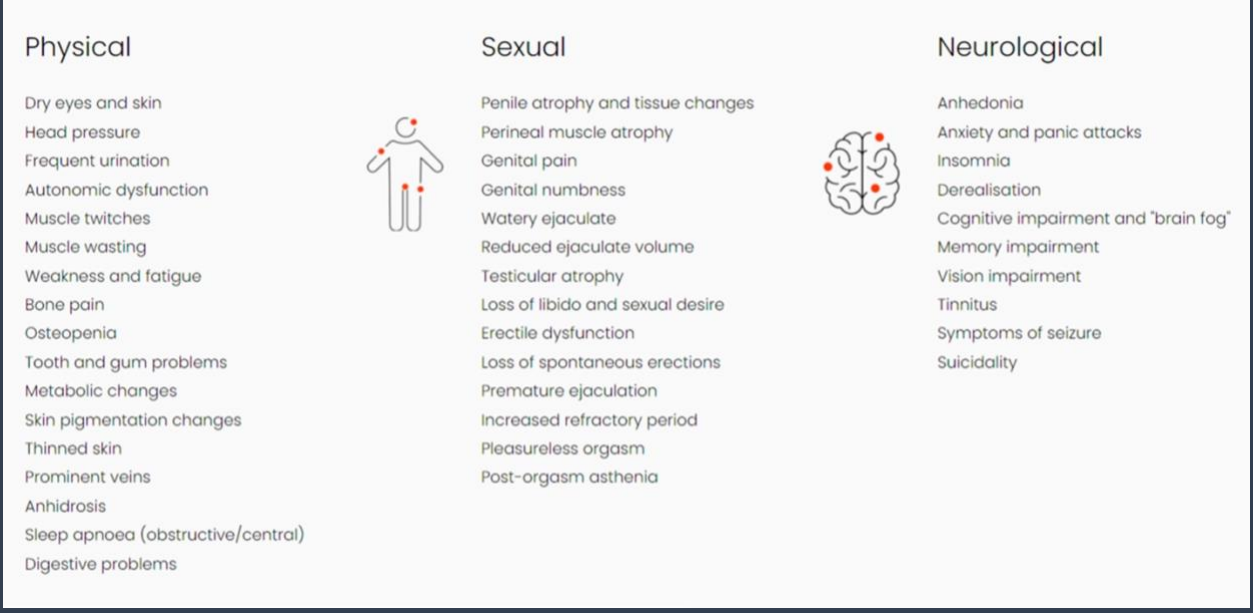
A Rare and Devastating Disease

In post-finasteride syndrome cases, symptoms typically onset or worsen after cessation of finasteride exposure. This is counterintuitive, of course, and serves as a capture of the uniqueness of this condition. On patient support forums, users have coined the term “crash” to describe the intensifying of previous symptoms and introduction of new symptoms after finasteride exposure has ceased. Unfortunately, despite extending far beyond what is typically understood as side effects, these symptoms are often characterized as such.

The disease is multi-systemic, involving symptoms across neurological, physical, and sexual domains. Symptoms are numerous, range from mild to devastating, and extend far beyond the commonly known (to the extent they are known) erectile dysfunction or depression. They are permanent and currently there is no cure.

[2] Yahoo! Groups was a collection of online discussion boards launched in 2001. The discussion board for post-finasteride syndrome was created in 2003, with membership quickly growing to over 1,000 individuals. In 2006, the forum moved to propeciahelp.com, which still functions as the largest patient support forum for the disease to this day.

[3] The first research on the condition was published in *The Journal of Sexual Medicine* in 2011 and discussed persistent sexual dysfunction after finasteride exposure in a cohort of seventy-one patients. Irwig, M. S., & Kolukula, S. (2011). Persistent sexual side effects of finasteride for male pattern hair loss. *The Journal of Sexual Medicine, 8*(6), 1747-1753. https://doi.org/10.1111/j.1743-6109.2011.02255.x



These symptoms are commonly reported in post-finasteride syndrome cases. Symptom information is supported by data from the survey discussed below.

Patient Survey: Key Insights

The administrators of PFS Network conducted a comprehensive patient survey from 2019 to 2021 which collected over 1,200 data points per participant with 427 respondents. Patients were recruited from the largest patient support forum for the disease.[4] From this came the following findings.

In post-finasteride syndrome patients, the number of health diagnoses rises in over 89% of cases following acquisition of the disease. Despite a public characterization that people reporting the disease have pre-existing mental health conditions, the incidence of pre-existing mental health conditions in patients was found to be lower than the general population.

Symptoms of the disease are most often multi-systemic, with 64% of participants experiencing at least one symptom in all three domains (neurological, physical, sexual). They are often numerous, with 77% experiencing five or more symptoms in at least one domain. And they often worsen after cessation of exposure: 73% experienced a sudden worsening after discontinuing the drug and the mean severity of every single symptom increased after cessation.

Developing the disease does not appear to be dependent on prolonged finasteride exposure, as 51% respondents were exposed for 200 days or less. In fact, the patients that experience the most severe symptoms are often the ones who were exposed for the shortest amount of time.

[4] See footnote two.

Over 72% of respondents were extremely dissatisfied with healthcare. Reasons include clinicians not being aware of or recognizing the disease, very few clinicians willing to provide support to people reporting these symptoms, and the lack of a treatment or effective methods for symptomatic relief.

If you are a researcher, regulator, or clinician wishing to inquire about our survey data, please feel free to reach out at contact@pfsnetwork.org.

Science: Published Research

Separate studies of post-finasteride syndrome, Di Loreto et al. 2014[5] and Howell et al. 2021,[6] have conducted an immunohistochemical evaluation of androgen receptor density and uncovered marked androgen receptor overexpression in affected patient tissue. In addition to finding an overexpressed androgen receptor, Howell et al. 2021 also conducted a microarray and found concurrent widespread deregulated gene expression of over 3,700 genes in patient tissue. Importantly, genes found differentially expressed in post-finasteride syndrome patients are relevant to signaling pathways that directly correlate with observed patient symptoms.

While a driving mechanism of the disease is not definitively known, all observations and research findings to date have supported the theorization that a persistent epigenetic alteration causes androgen receptor overexpression, which leads to the receptor not properly directing gene transcription:

> "A group of Italian researchers gave finasteride to rats and noticed that the number of androgen receptors in their brains went up. Moreover, the effects persisted long after the drug had been discontinued… [T]hey then called in men with PFS, took skin from the penis and found that the density of androgen receptors in men with PFS was about twice that of those without. Now, remember the idea of the testosterone bell curve and damping effects (little testosterone, little growth, more testosterone, more growth, even more testosterone, reduced growth)? I think this is what we are seeing here. With a greater concentration of receptors, the organ becomes more sensitive to testosterone and at a certain point, paradoxically, that sensitivity may shut down."
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> – Prof. Charles J. Ryan, M.D., Director, Division of Hematology, Oncology, and Transplantation, University of Minnesota, *The Virility Paradox* (2018).

[5] Di Loreto, C., La Marra, F., Mazzon, G., Belgrano, E., Trombetta, C., & Cauci, S. (2014). Immunohistochemical evaluation of androgen receptor and nerve structure density in human prepuce from patients with persistent sexual side effects after finasteride use for androgenetic alopecia. *PLoS ONE*, *9*(6), e100237. https://doi.org/10.1371/journal.pone.0100237

[6] Howell, S., Song, W., Pastuszak, A., & Khera, M. (2021). Differential gene expression in post-finasteride syndrome patients. *The Journal of Sexual Medicine*, *18*(9), 1479-1490. https://doi.org/10.1016/j.jsxm.2021.05.009

Current research efforts supported by the PFS Network are based on this hypothesis. For a more thorough and scientific illustration of it, please see here.

Separate studies of the disease, Khera et al. 2020[7] and Carlisle et al. 2022,[8] have also demonstrated penile vascular abnormalities, i.e., beyond just erectile dysfunction but actual, physical changes to patient penile tissue.

Other studies, Melcangi et al. 2013[9] and Melcangi et al. 2017,[10] found altered neurosteroid levels in the cerebrospinal fluid of post-finasteride syndrome patients.[11]

What Scientists Are Saying

"exposure to 5ARI could lead to permanent changes in genetic expression through unknown mechanisms which cause the changes we were able to measure and analyze."

— Howell et al.

"The present study supports the conclusion that 5ARI use may predispose to persistent sexual, genitourinary, psychocognitive, and anti-androgenic changes even after 5ARI therapy is discontinued."

— Khera et al.

"finasteride did not only affect, as expected, the levels of 5alpha-reduced metabolites of progesterone and testosterone, but also the further metabolites and precursors suggesting that this drug has broad consequence on neuroactive steroid levels of PFS patients."

— Melcangi et al.

[7] Khera, M., Than, J. T., Anaissie, J., Antar, A., Song, W., Losso, B., Pastuszak, A., Kohn, T., & Mirabal, J. R. (2020). Penile vascular abnormalities in young men with persistent side effects after finasteride use for the treatment of androgenic alopecia. *Translational Andrology and Urology*, *9*(3), 1201-1209. https://doi.org/10.21037/tau.2020.03.21

[8] Carlisle, M., Uloko, M., Yee, A., Goldstein, S., & Goldstein, I. (2022). Vascular, neurologic, and hormonal abnormalities in men with persistent sexual dysfunction after discontinuation of finasteride. *The Journal of Urology*, *207*(5), e620. https://doi.org/10.1097/JU.0000000000002592.07

[9] Melcangi, R. C., Caruso, D., Abbiati, F., Giatti, S., Calabrese, D., Piazza, F., & Cavaletti, G. (2013). Neuroactive steroid levels are modified in cerebrospinal fluid and plasma of post-finasteride patients showing persistent sexual side effects and anxious/depressive symptomatology. *The Journal of Sexual Medicine*, *10*(10), 2598-2603. https://doi.org/10.1111/jsm.12269

[10] Melcangi, R. C., Santi, D., Spezzano, R., Grimoldi, M., Tabacchi, T., Fusco, M. L., Diviccaro, S., Giatti, S., Carrà, G., Caruso, D., Simoni, M., & Cavaletti, G. (2017). Neuroactive steroid levels and psychiatric and andrological features in post-finasteride patients. *The Journal of Steroid Biochemistry and Molecular Biology*, 171, 229-235. https://doi.org/10.1016/j.jsbmb.2017.04.003

[11] Also, Howell et al. 2021 reported altered expression of genes implicated in neurosteroid synthesis and signaling as part of their findings.

Science: Upcoming Research

To further scientific understanding of post-finasteride syndrome, PFS Network was able to organize and raise funds for an epigenetics study conducted by Dr. Nadine Hornig at The Institute for Human Genetics at Kiel University, Germany. With the title of "Elucidating Epigenetic Mechanisms as a Possible Cause of Post-Finasteride Syndrome," it is examining chromatin structure and methylation of the androgen receptor regulatory region in patient tissue. Sample collection began in February 2023.

The organization has also been able to assemble a genetics study to be conducted by Prof. Alfonso Urbanucci at the University of Tampere, Finland. This study will perform and analyze a whole-genome sequencing (WGS) on patients to look for possible genetic factors that may predispose individuals to developing post-finasteride syndrome. If any should be found, they may assist in creating an animal model of the disease. The study is in the last stages of funding.

Disease Challenges

Other than the lack of an effective treatment and/or cure, the post-finasteride syndrome patient community faces numerous challenges, all of which impede desperately needed progress on the disease. For one, possible risk factors for developing post-finasteride syndrome are not yet known, which means that we do not know how someone being exposed to finasteride will be affected; it is completely variable. With this mind, it is challenging to provide informed consent to finasteride exposure at this juncture in time.

Furthermore, even after twenty years of patient reports on the condition, it continues to be poorly understood. As a result, patient experiences in the clinic are generally poor. This is due to several reasons, including a very small patient population (even for rare conditions), counterintuitive presentation (namely worsening after cessation and prolonged exposure not predisposing to developing the condition), lack of interest from scientific bodies, and lack of clinical reporting.

Specifically, the lack of clinical reporting on post-finasteride syndrome is one of the largest challenges the patient community faces. We have several reasons to be wary of this.

First, there is a large discrepancy between registrations on patient forums and reports in adverse event databases that match with symptoms of post-finasteride syndrome (as opposed to common side effects of exposure, which are less problematic and resolve over time). Additionally, a study by Baas et al. 2018[12] analyzed FAERS data from 2011 to 2014 and found that clinicians reported more than double the number of adverse events from the exposure dose of finasteride associated with benign prostatic hyperplasia (BPH) as they as they did adverse events from the exposure dose

[12] Baas, W. R., Butcher, M. J., Lwin, A., Althof, S., Kohler, T. S., & McVary, K. T. (2018). A review of the FAERS data on 5-alpha reductase inhibitors: implications for postfinasteride syndrome. *Male Sexual Dysfunction*, *120*, 143-149. https://doi.org/10.1016/j.urology.2018.06.022

associated with male pattern baldness (MPB). This is despite the researchers simultaneously finding many more total reports for the exposure dose associated with MPB.

Post-finasteride syndrome occurs vastly more frequently in individuals exposed for MPB, who are incidentally much younger than individuals exposed for other reasons. Per the PFS Network patient survey, only 1.87% of post-finasteride syndrome patients were exposed to finasteride for BPH and the mean age of patients at disease onset (and current ages of patients) was decades younger than ages at which BPH is often developed.

Taken together, the above indicates that cases of post-finasteride syndrome are likely not being properly reported in the clinic, as clinicians much more frequently report adverse events from the dose of finasteride given to older individuals whilst younger individuals appear drastically more likely to develop the disease. This could be the result of an erroneous assumption by many clinicians that patients' symptoms are not possible due to them not matching up with the warnings for finasteride, which is consistent with anecdotal observations from patient forums, patient testimony in this session, and the high dissatisfaction with healthcare found in the patient survey.

Lastly, suicidality and suicide have and continue to be a very real risk with this disease. There are countless cases of patients ending their life due to this condition, especially so among the most deeply impacted. Since many suicides go unreported, there is great difficulty in assessing the total number. The parent of a patient suicide will present in this session.

Patient/Caregiver Experiences

Caregiver #1, Parent of 37-year-old male

This parent spoke on behalf of her son, who possessed a healthy, active lifestyle prior to finasteride exposure for male pattern baldness. During the third week of exposure, he started experiencing "brain fog" and slight weight gain, which caused him to discontinue the drug a week later. The brain fog dissipated, so he decided to restart finasteride on a lower dosage. Within a few days of restarting, he experienced an extreme panic attack. He again ceased exposure, but this time his condition would persistently worsen.

He went on to develop severe anhedonia (the inability to feel pleasure), extreme anxiety, melancholy, issues with concentration, slurred speech, head pressure, dry skin and eyes, muscle wastage, joint pain, tinnitus, urinary incontinence, sexual dysfunction, and complete cessation of male pattern baldness, among other issues.

Caregiver #1's son was in constant mental anguish, spending most of his time crying and in despair. He had to move back home with her, and beyond being unable to continue with his employment, he was no longer able to read long-form material, watch television, or focus for short amounts of time. Having a complete lack of joy/positive

emotion and having lost all his interests, this parent said it was as if his life was being "sucked out of him." He remarked he no longer felt human.

This parent also described her son feeling invalidated and ridiculed when trying to explain the disease, including from some of the clinicians he visited, due to the current lack of awareness and understanding of the condition.

Ultimately, this parent's son would succumb to the disease after over a year and half of suffering, stating he was a "rational suicide": he did not wish to die, but he was unable to continue living in the state that post-finasteride syndrome left him in.

Patient #1, 30-year-old male

This patient was exposed to finasteride for male pattern baldness for a total of four days. After ending finasteride exposure, he quickly acquired brain zaps, anhedonia, cognitive impairment, memory impairment, bone pain, dry skin, muscle spasms and twitching, tinnitus, genital changes, loss of libido, and gynecomastia. He also bemoans a loss of creative thought processes, and an inability to feel motivation, joy, comfort, or feelings of romance.

Over time, he has had improvements in a few symptoms, namely fatigue, insomnia, and cognitive dysfunction. However, he is still dogged by all other symptoms mentioned and has suicidal thoughts due to them.

He described clinicians he visited (apart from one) disbelieving him due to lack of awareness and understanding of the condition, which was jarring to him. He asserted that he only underwent exposure because he was assured it was completely safe, and views acquiring the disease and experiencing the subsequent clinical difficulties as a deep breach of trust.

To treat the condition, he would accept high risk for medium benefit.

Patient #1 has been living with post-finasteride syndrome for one year and eight months at time of the Patient Listening Session.

Patient #2, 27-year-old male

This patient described having a healthy, fulfilling life before PFS, with the only worry coming from hair loss. He was presented with finasteride for male pattern baldness and exposed to the drug for three and a half weeks before cessation, stopping after beginning to experience disorientation and difficulty concentrating at work.

Patient #2 fully expected to return to normal after ceasing exposure, but instead developed insomnia which only allowed for him to get two to three hours of sleep each night for around a year. Six months after cessation of the drug, he experienced a dramatic worsening (or what has been referred to by patients as the "crash"). The

symptoms sexual dysfunction, lack of libido, severe genital atrophy, numb genitals, thin and brittle skin, intense lower back pain, changes in body hair, extreme depression and anhedonia, and severe suicidal thoughts were acquired. Male pattern baldness completely ceased.

This patient has had little symptomatic improvement but has been able to somewhat adjust to his reduced capabilities. He has had trouble receiving a diagnosis due to poor recognition of the disease and the fact it lacks distinct and easily identifiable biomarkers. He reports being frustrated with not having been informed about the possibility of persistent health issues after exposure to finasteride. If a treatment were to arise, he would tolerate high risk for medium benefit.

Patient #2 has been living with post-finasteride syndrome for two years at time of the Patient Listening Session.

Patient #3, 39-year-old male

This patient also reported having a fulfilling life before developing the disease. He was given finasteride for male pattern baldness and took the drug for ten days. He initially noticed that he could not feel his genitals (as they were numb) and could not maintain an erection. He also noticed having a “blank” mind with low-grade anxiety. These developments caused him to halt finasteride exposure.

In the following days and weeks, he began noticing more symptoms, such as extreme fatigue, insomnia, feelings of dizziness, “brain fog,” issues with concentration, memory impairment, anhedonia, slurred speech, slurred speech, and suicidal thoughts. He also has gone on to develop skin issues, swollen face, tinnitus, genital changes, and an inability to feel effects from alcohol.

He notably detailed being unable to feel emotions at the funeral of a loved one, describing post-finasteride syndrome as a “mental death.”

Patient #3 has been living with post-finasteride syndrome for twelve years at time of the Patient Listening Session.

Patient #4, 29-year-old male

Patient #4 was highly physically active and a proactive individual before getting post-finasteride syndrome. During finasteride exposure, he developed slurred speech, extreme “brain fog,” memory impairment, and anhedonia. He had three MRIs, two EMGs, and one EEG, all of which returned normal results (which highlights the difficulty in receiving a diagnosis for this condition and more broadly, for functional neurologic disorders).

Fifteen months into taking the drug, he ceased exposure and reports suddenly losing eighteen pounds with no change in diet or exercise. He began experiencing skin changes at this time, which has caused his skin to become very stretchy and dough-

like. Other symptoms he would eventually develop after discontinuation include penile curvature, anxiety, and insomnia. Unfortunately, he has had no improvement in his symptoms, stating, “I am not the same person that I once was.” The patient then notes his personality has become shy, nervous, and quiet, and that he now has a difficult time connecting with his family, friends, and coworkers.

Patient #4 has been living with post-finasteride syndrome for two years and five months at time of the Patient Listening Session.

Patient #5, 21-year-old male

This patient was given finasteride for mild hair thinning and unaware of the possibility of permanent, serious health issues after finasteride exposure. Within a few weeks, he noticed a complete absence of libido (to the point intercourse seemed “alien,” he said) and penile shrinkage. A few days later, he developed severe memory impairment (including episodic and semantic memory loss), impaired executive functioning, and anhedonia. He discontinued exposure, but nothing changed.

He describes continuing with his symptoms in a debilitating yet stable state for a year and ten months after cessation, until they started worsening. In addition to his initial symptoms, he now has slowed thinking, a loss of inner monologue, issues following conversations, issues accessing mental representations, issues with depth perception, issues forming a mental map of his surroundings, inaccurate auditory spatial perception, visual snow, inability to feel sense of weight when picking objects up or sense of force when baring down on objects, bone and joint pain, extremely rubbery and pale skin, numb skin, tinnitus, total anorgasmia, and complete cessation of hair loss.

This patient detailed his quality of life living with this disease as being substantially negatively impacted. From the time he acquired the disease until he began worsening nearly two years later, he was able to continue full time at college and hold internships. However, he noted that he had to aggressively structure his activities around his memory impairment (for example, he could not take the specific courses he wanted to take nor the number of courses he wanted to take). Unfortunately, he has been disabled since he began to worsen around ten months ago. He says he effectively has no quality of life, as he cannot read long-form, watch television, or participate in many other activities, mainly due to his impaired cognition and memory.

In a treatment, he would accept high risk for medium benefit.

Patient #5 has been living with post-finasteride syndrome for two years and nine months at time of the Patient Listening Session.

Question and Answer

FDA staff asked if women could acquire the condition. President of PFS Network Mitch Sabine answered, saying that they can but he is only aware of them in single digits

within the patient community. Female post-finasteride syndrome patients are very rare, he noted, as 1) incidence rates of the condition are rare and 2) females are rarely exposed to finasteride. Sabine also noted that current research efforts are solely including males in order to maintain uniformity, in addition to prospective difficulty in identifying female patients to participate due to rarity.

FDA staff asked if patients would take a potential drug/treatment to reduce their symptoms rather than completely resolving them and what level of risk tolerance would be acceptable. One patient responded saying he would and his risk tolerance for a therapeutic relief is about as high as you can get. Another patient cautioned that many patients have made themselves worse by attempting experimental treatments, so he would be wary.

Lastly, FDA staff asked patients which symptom has had the greatest impact on their life. Four patients responded, and all of them agreed they consider anhedonia to be most detrimental. They said it substantially (and in some cases totally) subtracts from the human experience and makes them question if their life should be continued. Mr. Sabine affirmed, asserting that severe anhedonia causes many patients to consider suicide.

Attendees

FDA Divisions Represented

Office of the Commissioner (OC) – 2 *offices*

- OC/OCPP/PAS – Office of Clinical Policy and Programs/Patient Affairs Staff (*organizer*)
- OC/OCPP/OOPD – Office of Clinical Policy and Programs/Office of Orphan Products Development

Center for Biologics Evaluation and Research (CBER) – 1 *office/division*

- CBER/OCD/PS – Office of the Center Director/Policy Staff

Center for Devices and Radiological Health (CDRH) – 3 *offices/divisions*

- CDRH/OPEQ/OHTIII/DHTIIIC – Office of Product Evaluation and Quality/Office of Health Technology III/Division of Health Technology III C
- CDRH/OPEQ/OHTIV/DHTIVA – Office of Product Evaluation and Quality/Office of Health Technology IV A
- CDRH/OSPTI/DAHRSSP/PSE – Office of Strategic Partnership and Technology Innovation/Division of All Hazards Response Science and Strategic Partnership/Patient Science and Engagement

Center for Drug Evaluation and Research (CDER) – 10 *offices/divisions*

- CDER/OCOMM/PASES – Office of Communications/Professional Affairs and Stakeholder Engagement Staff
- CDER/OND – Office of New Drugs
- CDER/OND/ODES/DCOA – Office of New Drugs/Office of Drug Evaluation Science/Division of Clinical Outcome Assessment

- CDER/OND/OII/DDD – Office of New Drugs/Office of Immunology and Inflammation/Division of Dermatology and Dentistry
- CDER/OND/ORDPURM – Office of New Drugs/Office of Rare Diseases, Pediatrics, Urology and Reproductive Medicine
- CDER/OND/ORDPURM/DRDMG – Office of New Drugs/Office of Rare Diseases, Pediatrics, Urology, and Reproductive Medicine/Division of Urology and Reproductive Medicine/Division of Rare Diseases and Medical Genetics
- CDER/OND/ORDPURM/DUOG – Office of New Drugs/Office of Rare Diseases, Pediatrics, Urology and Reproductive Medicine/Division of Urology, Obstetrics and Gynecology
- CDER/OSE/OMEPRM/DRM – Office of Surveillance and Epidemiology/Office of Medication Error Prevention and Risk Management/Division of Risk Management
- CDER/OSE/OPE/DEPII – Office of Surveillance and Epidemiology/Office of Pharmacovigilance and Epidemiology/Division of Epidemiology II
- CDER/OSE/OPE/DPVI – Office of Surveillance and Epidemiology/Office of Pharmacovigilance and Epidemiology/Division of Epidemiology IV

Non-FDA Attendees

Reagan-Udall Foundation

Disclaimer

Discussions in FDA Patient Listening Sessions are informal. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants. This report reflects PFS Network's account of the perspectives of patients and caregivers who participated in the Patient Listening Session with the FDA. To the extent possible, the terms used in this summary to describe specific manifestations of post-finasteride syndrome (PFS), health effects and impacts, and treatment experiences, reflect those of the participants. This report is not meant to be representative of the views and experiences of the entire post-finasteride syndrome patient population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report.

To learn more about PFS Network and our awareness and research efforts, please visit www.pfsnetwork.org

Contact us:
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