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Inside this issue

Post-Finasteride Syndrome (PFS) Update: Point/Counterpoint

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At the ISHRS 2015 Annual Scientific Meeting in Chicago, we heard an update on the constellation of symptoms that has come to be known as Post-Finasteride Syndrome (PFS). The update was presented by guest speaker Dr. Mohit Khera, Associate Professor in the Department of Urology at Baylor College of Medicine where he specializes in male infertility and sexual medicine. Based on the Audience Response System responses of those attending, it was obvious that his presentation influenced the audience's practice opinion toward finasteride. As a speaker and panel member, I am concerned that the format of the session did not allow for clarification of some of the unsubstantiated conclusions that were made in Dr. Khera's presentation, and did not allow for a complete discussion of all potential conflicts of interest (COI) he may have had concerning the topic. Furthermore, a counterpoint discussion with the audience was not taken.

Dr. Khera did mention a COI, that his study was funded by a grant from the Post-Finasteride Syndrome Foundation. This foundation was started by two physicians whose son developed severe depression during a period in his life when he had also taken finasteride. Their website describes the organization's focus to increase global awareness of the "devastating and life-altering impact finasteride can have on the sexual, mental, and physical health of men." While there are a number of clinician and research members, including Dr. Khera, of the International Society of Sexual Medicine and Sexual Medicine Society of North America who have strong opinions that PFS is a real entity, no studies to date have established that PFS is an actual entity, defined the at-risk patient population, or noted the actual incidence or the mechanism that could explain persistent symptoms. He referenced the often quoted publications of Dr. Michael Irwig, which have been heavily criticized for a patient database obtained from a website with a strong bias. Conclusions from his "studies," which have extreme selection bias and lack scientific controls, should be regarded with skepticism. Additionally, Dr. Khera is an Associate Editor of *The Journal of Sexual Medicine,* which has published several of these and related publications.

Beyond the above issues, I wish to address several points in Dr. Khera's presentation: male breast tissue, infertility, and prostate cancer.

Gynecomastia is a well-documented adverse event reported in up to 2% of men taking 5-alpha reductase inhibitors (ARIs). Dr. Khera raised an alarm concerning male breast cancer quoting a study in which 4 out of 1,554 men taking finasteride developed breast cancer, 200 times the general population. In my review of finasteride and dutasteride double-blinded, controlled studies of 28,000 men taking finasteride vs. placebo, 8 cases of breast cancer were reported, of which 3 were taking finasteride and 5 placebo. Of 22,400 men taking dutasteride vs. placebo, 3 cases of breast cancer were reported, 2 with dutasteride and 1 placebo. Based on these two large cohort studies, there is no statistical evidence to arrive at the conclusion of an increased incidence of breast cancer in men using 5 ARIs. While the patient information packets for finasteride and dutasteride mention post marketing associations with breast cancer, 50 cases have been reported in the world's literature, and 26 developed in less than a year within starting finasteride.

The Million Women Study in the United Kingdom was set up to investigate the effects of specific types of HRT [hormone replacement therapy] on incident and fatal of breast cancer.[1] It concluded that the risk of breast cancer increased with increasing total duration of HRT use. The report in men of so many cases within one year of starting the drug suggests that the cancers were not induced by finasteride. These cancers were already present and detected due to early discovery.

A review of this issue in the November 2013 *Journal of Urology* concluded that "the lack of an association suggests that the development of breast cancer should not influence the prescribing of 5 ARI therapy."[2]

During the Q&A session, Dr. Khera recommended against using finasteride in couples attempting conception. While his expertise is in infertility, there is ample data to support the opposite opinion that there is insufficient finasteride in normal ejaculate volume to adversely affect a potentially pregnant woman, or to reduce spermatogenesis or infertility in healthy men chronically taking finasteride.[3] The few studies with small populations implicating a reduction in male fertility appear to be in subfertile men or those with an underlying condition such as varicocele.[4]

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President's Message

Kuniyoshi Yagyu, MD, FISHRS *Tokyo, Japan* nhttokyo@kioicho.jp

The ISHRS has been growing and now has over 1,200 members from 73 countries and a total 91 Fellow Members in the 2015-2016 program year. The ISHRS offers many educational programs for members. These programs provide members the latest information about hair restoration treatments. The designation of "Fellow of the ISHRS" is an honorable qualification with the noblesse oblige. Fellows of the ISHRS are expected to play leading roles through voluntary activities at many meetings including Regional Workshops, Regional Meetings, and the World Congress of the ISHRS.

The ISHRS provides ample learning opportunities to its members. The ISHRS hopes that many members will attend ISHRS-sponsored Regional Workshops and the World Congress of the ISHRS, as they attempt to improve their practice. As we begin a new year, I would like to summarize activities of the ISHRS in 2016:

- April 1-3, 2016, Dr. Osman Tayfun Oguzoglu, ISHRS FUE Workshop, Istanbul 2016, in Istanbul, Turkey
- May 5-7, 2016, Dr. James Harris, ISHRS Regional Workshop, Surgical Assistant Training Program: Graft Preparation and Placement (FU-Strip and FUE), in Denver, Colorado, USA
- June 10-12, 2016, Dr. Bessam Farjo, ISHRS Regional Workshop, European Hair Transplant Workshop, in Manchester, United Kingdom
- July 29-30, 2016, Dr. James Harris, 2016 FUE-Palooza, in Denver, Colorado, USA
- October 19-22, 2016, the 24th World Congress of the ISHRS, in Panama City, Panama

The ISHRS will give a US$200.00 coupon to each registrant who attends an ISHRS-sponsored Regional Workshop. The coupon can be used only for discounted registration fee at the 2016 World Congress of the ISHRS in Panama City. This is a new incentive for ISHRS members who attend both an ISHRS-sponsored Regional Workshop and the ISHRS World Congress in 2016!

There are many more educational possibilities. If you log in to the Members Only section on the ISHRS website, you can familiarize yourself with the many resources for members only, some of which include many excellent surgical videos in the Video Library, Recorded Sessions from past Annual Meetings, and access to past issues and a searchable database of article archives of the bimonthly Forum newsletter.

In addition, the ISHRS has several educational enduring materials available including recorded webinars on various topics, the Basics in Hair Restoration Surgery Lecture Series, and high definition surgical videos. We also offer the online Cheryl Pomerantz Surgical Assistants Training Resources Center, which houses a load of invaluable information and videos that helps doctors train their assistants.

The ISHRS hopes that many members utilize these opportunities and materials to improve their medical practice. The ISHRS also hopes that members will recommend to their friends and colleagues to join the ISHRS so many people can enjoy these educational materials.

Your membership dues include subscriptions to journals and publications such as *Hair Transplant Forum International* and *Dermatologic Surgery*. Other member benefits include ISHRS CME Awards, 2016 Research Grants, a Fellowship Training Program, the Annual Giving Fund, and Operation Restore.

The ISHRS is opposed to assistant-performed surgery. It is not our goal to police doctors. The ISHRS believes that the members should take ethics in medicine seriously.

The ISHRS wishes to be a society that supports education, ethics, and medical science.

The ISHRS hopes that patients suffering from hair loss will receive safe surgery and enjoy the best outcome of hair restoration treatment.

I wish you all a peaceful and happy new year!◆

Co-editors' Messages

Mario Marzola, MBBS *Adelaide, South Australia* editors@ISHRS.org

Dear readers, I am very concerned with the increasing discussion and publicity given to post finasteride syndrome (PFS). It is gaining a momentum of its own, receiving prominence in the media and electronic forums. We live and work in a litigious society. There are lawyers looking over our shoulder when we treat our patients, hoping to find a reason to make a case against us.

We as doctors try to practice safe medicine for our patients but we are being forced to practice defensive medicine to avoid being sued.

There comes a time when enough is enough, when the legal intrusion into the sacrosanct doctor/patient relationship is too much. Then it is time to say to the patient… that after due study and consideration, and explaining the side effects in detail and in writing, I believe that finasteride is the best drug available to stabilize your hair loss.

I will tell them about PFS and place it into perspective. They walk out of my office with an incredible amount of information and websites to go to. And a prescription for 12 months of finasteride treatment.

They know that they are welcome back within that time should they have a concern or doubt of any type. Dr. Edwin Epstein, chair of the ISHRS Task Force on Finasteride Adverse Event Controversies, summarises our position well in the leading article of this edition.

Dr. William Parsley wrote recently on another subject but using these words:

"None of us want to harm our patients, but the flip side is to be so cautious that we won't help the huge number of patients who would do very well."

This first issue of the *Forum* for 2016 has a distinctive Japanese flavour. Starting with our congenial and very professional president, Dr. Kuniyoshi Yagyu, we also have his story on the formation and development of the Japanese Society of Clinical Hair Restoration, plus Dr. Jennifer Martinick's report on that society's recent meeting.

We look forward to a wonderful year of discovery in 2016, new ways to help our patients, better outcomes, better pharmaceuticals, cell based therapies, and, if we do need surgery, make it minimally invasive. Let's have a wonderful year.◆

Robert H. True, MD, MPH, FISHRS *New York, New York, USA* editors@ISHRS.org

In this issue's Letters to the Editors, Drs. Bill Rassman and Sharon Keene continue their discussion about the critical need for the ISHRS to actively pursue comprehensive training for newcomers to our field. As a society, we have always provided educational opportunities for beginners through the Beginners courses at our annual meeting, through regional workshops, and via enduring materials as well as a Newcomers Program.

Over the past two years, it has been a pleasure for me to be part of the faculty for the Saint Louis 360 Hair Transplant Workshop (SLU). This course, which is designed for both beginner physicians and technicians, is an outstanding educational experience and in my opinion a must for beginners. Most beginner workshops are a single day and provide limited hands on opportunity. The SLU is an intensive 3½ day course including comprehensive instruction in medical and surgical management of hair loss disorders along with many hours of hands-on instruction. The St. Louis University Practical Anatomy lab is a remarkable teaching facility. Cadaver tissue is often difficult to work with and fails to reproduce the feel of live skin. However, this year we had an opportunity to work with fresh frozen cadaver tissue, which significantly better approximates live tissue. I think this was the first time in all my years of teaching FUE that I felt we could give the student a meaningful feel of live FUE. Please look at the meeting review in this issue for further detail, and please consider recommending it to beginners in your clinic and region.

In my opinion, whether Post-Finasteride Syndrome is a real entity or not remains unclear. Since it was suggested in 2012, it has been a topic of sincere concern and evaluation in our field and by our Society. The problem is that the science for its existence still remains suggestive at best and at the lowest level of evidence based medicine—editorials, opinion, and case series and reports (Figure 1). Given the lack of carefully controlled studies that eliminate bias and confounding factors, we really don't know at this point if finasteride use is anything more than an association, not a cause. Despite my uncertainty, I do continue to discuss PFS and the FDA prescribing information when prescribing finasteride. I appreciate the thorough contributions of Drs. Edwin Epstein, Robert Bernstein, and Bradley Wolf on this topic in this issue.◆

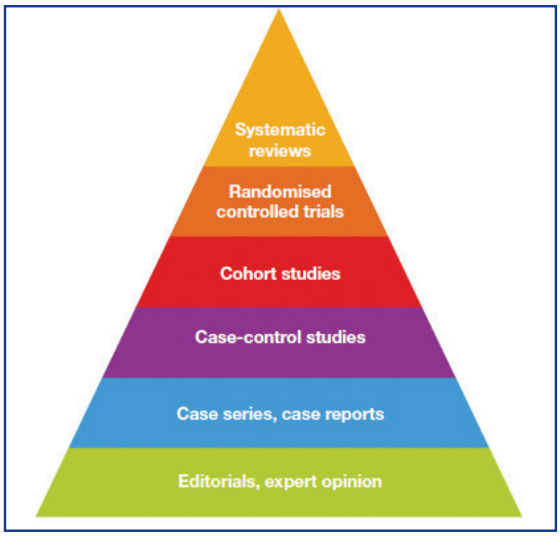

Figure 1. Evidence Based Medicine Pyramid

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Vision: To establish the ISHRS as a leading unbiased authority in medical and surgical hair restoration.
Mission: To achieve excellence in medical and surgical outcomes by promoting member education, international collegiality, research, ethics, and public awareness.

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Editorial Guidelines for Submission and Acceptance of Articles for the Forum Publication

1. Articles should be written with the intent of sharing scientific information with the purpose of progressing the art and science of hair restoration and benefiting patient outcomes.
2. If results are presented, the medical regimen or surgical techniques that were used to obtain the results should be disclosed in detail.
3. Articles submitted with the sole purpose of promotion or marketing will not be accepted.
4. Authors should acknowledge all funding sources that supported their work as well as any relevant corporate affiliation.
5. Trademarked names should not be used to refer to devices or techniques, when possible.
6. Although we encourage submission of articles that may only contain the author's opinion for the purpose of stimulating thought, the editors may present such articles to colleagues who are experts in the particular area in question, for the purpose of obtaining rebuttal opinions to be published alongside the original article. Occasionally, a manuscript might be sent to an external reviewer, who will judge the manuscript in a blinded fashion to make recommendations about its acceptance, further revision, or rejection.
7. Once the manuscript is accepted, it will be published as soon as possible, depending on space availability.
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9. A completed Author Authorization and Release form—sent as a Word document (not a fax)—must accompany your submission. The form can be obtained in the Members Only section of the Society website at www.ishrs.org.
10. All photos and figures referred to in your article should be sent as ***separate*** attachments in JPEG or TIFF format. Be sure to attach your files to the email. Do NOT embed your files in the email or in the document itself (other than to show placement within the article).
11. Images should be sized no larger than 6 inches in width and should be named using the author's last name and figure number (e.g., TrueFigure1).
12. Please include a contact email address to be published with your article.

Submission deadlines:
February 5 for March/April 2016 issue
April 5 for May/June 2016 issue
June 5 for July/August 2016 issue

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Notes from the Editor Emeritus

William M. Parsley, MD, FISHRS *Louisville, Kentucky, USA* parsleyw@bellsouth.net

Judgment

For someone starting hair restoration surgery in early 1974, the development of this field has been nothing short of incredible. For patterned baldness, this field didn't even exist until 1958. We were using large round grafts, but immediately there were some innovators trying to work with smaller grafts, reducing transection and improving donor harvesting. In spite of this, it took 25 years before the next big advancement, minigrafts, became mainstream. With minigrafts came divided round grafts, multi-blade harvesting with strip dissection, multi-unit grafts, slit grafts, and elliptical recipient punches. Minigrafts had a good run of about 10 years and then microscopically dissected follicular unit grafting was developed. While a few steps led to this development in 1994, the final step was so significant that it is still the gold standard 20 years later. This isn't to say the introduction of follicular unit extraction (FUE) of the early 2000s wasn't significant; it was very significant and currently often dominates our meetings. Today's skills and techniques are beyond the dreams of most of the older practitioners. Properly done, even today's hair surgeons can often not be sure that a given patient has had a transplant.

Technical skills are critical to having good results, but are they everything that is needed? Let's examine this. Knowledge comes first as it is the accumulation of all of the facts and studies done in our field. Then comes wisdom, which is the understanding of how all of these facts and studies fit together to realize their relative significance. Wisdom is needed to explain the significance of this knowledge to colleagues and patients in a way they will understand. Ethics is practicing honorably within a code of behavior, using your wisdom and, of course, your field's code of ethics. Compassion is caring about your patient in all phases of your medical interaction. To be the doctor or assistant that you wish to be, all of these are required. Some can be taught and some have to come from within, but all can be cultivated. Most of the physicians and assistants within the ISHRS have these qualities, some having them in abundance. Why would you bother to take time off from work and home and pay to come to the meetings if you didn't want to learn and to better understand your field? If you didn't have compassion, why would you want to give your patients the best the field has to offer?

But there is one quality that remains elusive, and it is a very important quality. That quality is judgment. Judgment is taking in all of the above and then putting them to use when you take action. On whom do you operate? On which patients do you try medication first? How do you gear your treatment to the changes that will certainly affect that patient over the course of time? In this aspect, physicians seem to be all over the map, but it isn't easy. Judgment is more difficult to cultivate and use than the above qualities. At the heart of the matter is what will happen to the patient over the course of time? Years ago, follow-up pictures were shown at 2-5 years as if they validated the physician's decision to operate, only to find that the results often eroded with time and left a disillusioned or bitter patient to finish out his last 40-50 years of life. Our industry is better than that now. We seem to have never appreciated enough that hair loss is not just relentless but that it is also unpredictable. Even the life of the donor grafts is unpredictable.

Many factors can test your judgment to do something questionable: the panicky 20-year-old with developing Norwood VI baldness because we worry he might hurt himself or become a social introvert, the young patient wanting the full prepubertal hairline because he doesn't want an "old man" hairline at 26, the Norwood VII who wants everything covered, a female with diffuse unpatterned hair loss telling you that even the slightest improvement will make her happy. When is it okay to do something you believe is ultimately inadvisable in order to take care of the immediate situation or simply to satisfy a patient's request? When patients tell you that all they care about is their immediate situation, that even slight improvement will be worth it, that they won't continue to bald because that is their family pattern—you know that isn't likely to be ultimately true and that they will regret bad decisions. Twenty-year-olds will care about their looks at 40 regardless of what they are telling you. Maybe they tell you that another doctor—whom you believe to have fewer skills—has already said he or she will operate. Does that give you the green light? How sensitive are you to any green light that will allow your conscience to operate on a patient you truly feel would best be served by bypassing surgery? The answer to none of these questions is always evident. Judgment and ethics are needed to deal with each person as a totally separate case, but we hair surgeons are not short order cooks. We are their doctors and should be their protectors.

No one ever operates on sure things. Post-transplant cicatricial alopecia can develop, unexpected onset of rapid hair loss can develop even at an older age, and scars can be unpredictable. All you can do is evaluate each patient to the best of your ability, and operate only when you truly think it is in the patient's best interest, and with a pattern that you feel should hold up enough as the patient ages to be better than if the patient had no surgery. You should be careful so as not to allow wishful thinking to give your conscience permission to operate on a poor candidate. You can always delay a while until you have a little clearer idea of the patient's ultimate hair loss. No one has a crystal ball, and the patient should be educated as to the "unpredictabilities." With time, each one of us will have been wrong numerous times; and it will at least be comforting to know that you acted on what you felt was in the patient's best interest.

Ultimately, it comes down to judgment—and that can be cultivated even if never perfected.◆

PFS Update *from front page*

Attendees may have left with the impression that 5 ARI cause high-grade prostate cancer. The original Prostate Cancer Prevention Trial (PCPT) study found a higher percentage of high-grade prostate cancer in men taking finasteride; however, subsequent analysis found multiple counter arguments against this increase being a real risk. Analysis of this same cohort 18 years later showed no significant difference between the two groups in rates of overall survival or survival after diagnosis of prostate cancer. Based on this information, it can be concluded that the increased Gleason scores initially noted were due to better detection by biopsy in prostates that were smaller from the effects of finasteride, and possibly increased sensitivity of PSA testing.

Since the approval of finasteride to treat androgenetic alopecia, the majority of members of the ISHRS have successfully helped thousands of patients. As physicians and clinicians, our primary concern is patient safety, and our desire is to discover the truth about this drug.

Placebo controlled clinical trials are needed to assess whether or not a causal link to finasteride exists as well as the incidence and possible etiology of central nervous system (CNS) and sexual side effects, and determining which patient populations may be at risk. The significant psychological aspects of potential side effects, magnified by sensationalized information on the internet and in the media, complicate the interpretation of data obtained outside of controlled, blinded scientific studies.

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On page 7 is Dr. Robert Bernstein's very comprehensive information sheet and consent form that he gives his patients. Most consent forms used by our colleagues are not this detailed. For that reason, we have also included the consent form used by Dr. Paul Rose in his office. Each one of us should choose a consent form with which we are comfortable and suits the laws of the country in which we live. —MM

Bernstein's Consent and Information on Finasteride and Propecia®

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Propecia® (finasteride 1mg) is an oral medication, manufactured by Merck Pharmaceuticals, that blocks the conversion of testosterone to dihydrotestosterone (DHT), the hormone largely responsible for male pattern baldness. It does this by inhibiting the action of the type II 5-alpha reductase enzyme that is present in higher concentration in and around the hair follicles of balding men with androgenetic alopecia.

Finasteride is the only FDA approved medication for hair loss in men. It became available as the brand Propecia (finasteride 1mg) in December 1997. It is now generic. The same drug, under the brand name Proscar (finasteride 5mg) has been approved for the treatment of prostate enlargement since 1992.

Finasteride produces a rapid decrease in serum DHT concentration. Lowering DHT appears to inhibit the miniaturization (shrinking) of affected hair follicles and helps restore miniaturized hair follicles to regrow visible hair. Circulating levels of testosterone and estradiol were increased by approximately 15% as compared to baseline in the first year of treatment, but these levels were within normal range.

Studies have shown that after five years of treatment, 90% of men taking finasteride maintained their hair or increased hair growth. At five years, 48% of men treated with PROPECIA demonstrated an increase in hair growth, 42% were rated as having no change (no further visible progression of hair loss from baseline) and 10% were rated as having lost hair when compared to baseline. In comparison, 6% of men treated with placebo demonstrated an increase in hair growth, 19% were rated as having no change and 75% were rated as having lost hair when compared to baseline.

The effects of finasteride are confined to areas of the scalp that are thinning, but where there is still some hair present. It does not seem to grow hair in completely bald areas. Therefore, the major benefit of finasteride seems to be in its ability to slow down or halt hair loss, or regrow hair in parts of the scalp, where the hair is thin. The effects of finasteride peak at one to two years. Finasteride continues to be effective for at least 5 years in slowing down, or preventing additional hair loss.

The benefits of finasteride will stop if the medication is discontinued. Over the two to six months following discontinuation, the hair loss pattern will generally return to the state that it would have been reached if the medication had never been used.

Using PROPECIA

PROPECIA is an oral medication that should be taken once daily with or without meals. Patients must take Finasteride for one year or longer before its effects in preventing hair loss and re-growing hair can be accurately assessed. Finasteride takes up to a year or more to exert its full effects in both preventing hair loss and in re-growing hair.

During the first six months you may note some thinning of your existing hair. This may be due to either progression of your hair loss before finasteride has had a chance to work or some shedding of miniaturized hair that makes way for the new healthy hair to grow. It is important to be patient during this period. You should continue the medication for at least one year before you and your doctor can assess its benefits.

Sexual Side Effects

Side effects from finasteride at the 1-mg dose are uncommon. The one-year drug related side effects were 1.5% greater than in the control group. The data showed that 3.8% of men taking finasteride 1mg experienced some form of sexual dysfunction verses 2.1% in men treated with a placebo. The five-year side effects profile included: decreased libido (0.3%), erectile dysfunction (0.3%), and decreased volume of ejaculate.

Most reported cases of sexual dysfunction occurred soon after starting the medication, but there have been reports of sexual dysfunction that have occurred at later points in time. The sexual side effects were reversed in those who discontinued therapy, and in 58% of those who continued treatment. After the medication was stopped, side effects generally disappeared within a few weeks. There have been anecdotal reports where side effects have persisted after discontinuation of therapy. This had been referred to as "Post-finasteride syndrome."

When finasteride is discontinued, only the hair that had been gained or preserved by the medication is lost. In effect, the patient returns to the level of balding where he would have been had he never used the drug in the first place. No drug interactions of clinical importance have been identified.

Finasteride Label Changes – 2012 (Summary)

On April 11, 2012, the U.S. Food and Drug Administration (FDA) announced changes to the professional labels for Propecia (finasteride 1 mg) and Proscar (finasteride 5 mg) to expand the list of sexual adverse events reported to FDA as some of these events have been reported to continue after the drug is no longer being used (note that erectile dysfunction after stopping use of these drugs was added as a known event in 2011). The new label changes include:

- A revision to the Propecia label to include libido disorders, ejaculation disorders, and orgasm disorders that continued after discontinuation of the drug.
- A revision to the Proscar label to include decreased libido that continued after discontinuation of the drug.
- A revision to both the Propecia and Proscar labels to include a description of reports of male infertility and/or poor semen quality that normalized or improved after drug discontinuation.

Despite the fact that clear causal links between finasteride (Propecia and Proscar) and sexual adverse events have NOT been established, the cases suggest a broader range of adverse effects than previously reported in patients taking these drugs.

Only a small percentage of men using these drugs have experienced a sexual adverse event. During treatment with Propecia, 3.8% of men had reported one or more adverse sexual experiences as compared to 2.1% men who did not receive Propecia (received placebo). This represents a 1.7% difference.

For Propecia, the FDA's Agency's Adverse Events Reporting System (AERS) database between 1998 and 2011 found 59 cases of reported sexual dysfunction that lasted for at least three months following discontinuation of Propecia, and included erectile dysfunction, decreased libido, problems with ejaculation and orgasm disorders.

The FDA has not established a cause and effect relationship between finasteride and the sexual adverse events that continued after stopping drug use. The FDA believes that finasteride remains a safe and effective drug for its approved indications. Healthcare professionals and patients should consider this new label information when deciding the best treatment option.

See: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm299754.htm

Post-Finasteride Syndrome (PFS)

Post Finasteride Syndrome (PFS) is the term applied to reports of significant sexual, neurological and physical side effects, such as erectile dysfunction, depression, clouded thinking "brain fog," penile numbness, penile shrinkage, and loss of libido, that persist in men who have taken and then discontinued finasteride. Studies in progress are trying to better understand the incidence, cause and risk factors of PFS. More information on PFS can be found on the website: http://www.pfsfoundation.org/

Fertility

Finasteride may decrease fertility in some men. The effects may be due to changes in the composition of ejaculate and/or a reduction in sperm count. The effects appear to be reversible on discontinuing the medication.

Effects on Breast Tissue

Adverse reactions related to the breast, including breast tenderness or breast enlargement (gynecomastia), occurred in 0.4% of men taking finasteride 1-mg (PROPECIA), but this was no greater than in the control group. In a large study published in the Journal of Urology in 2013, the authors reported: "The lack of an association in our study suggests breast cancer development should not influence prescribing of 5ARI therapy."

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Other Adverse Reactions

Other, uncommon side effects, included hypersensitivity reactions including rash, pruritus (itching), urticaria (hives), swelling of the lips and face, testicular pain, mood changes (including depression) and cognitive changes (sometimes referred to as "brain fog").

Finasteride and Prostate Cancer

The results of an 18-year, 18,000 patient study published 8-14-2013 in the New England Journal of Medicine, showed that taking finasteride 5mg a day does not increase the likelihood of death from prostate cancer. Early results from the same study had suggested that finasteride might increase the risk of developing higher grade tumors; however, follow-up results from the long-term study show that men taking the drug do not have an increased risk.

Additionally, the results of the study show that taking finasteride actually decreases the likelihood of a diagnosis of prostate cancer in men by 30% and a diagnosis of "low-grade" cancer in men by 43%. By shrinking the healthy prostate tissue, finasteride decreases the chances of a false positive result in PSA screening tests and can avoid unnecessary surgery.

Caution during Pregnancy

Women should not handle crushed or broken PROPECIA tablets when they are pregnant, or may potentially be pregnant, because of the possibilities of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. Exposure of pregnant women to semen from men treated with PROPECIA has not been shown to pose any risk to the fetus.

Blood Donation

Patients taking finasteride should not donate blood as this blood may potentially be given to pregnant women.

Generic Finasteride

For those wanting to take generic finasteride, we recommend buying a pill cutter at the pharmacy and taking ¼ of a 5mg tablet every day. Although there is no scientific data insuring that this method of taking finasteride will be as effective as Propecia 1mg a day, the pharmacology of the drug suggests that these methods are equivalent. Please divide only one pill at a time. The pill does not need to be divided into 4 equal parts.

When dividing these tablets, remember that there is a potential risk to pregnant women from handling broken or crushed tablets (see Caution during Pregnancy).

Off-Label Dosing

There are no scientific studies that prove that increasing the dose will have any additional beneficial effects on hair loss. There are published data demonstrating that 5 mg is no better than 1 mg in controlled clinical trials. In practice, however, doctors may increase the dose when someone has been on the same dose of medication for 3-5 years and then stops responding (begins to lose hair after being stable). It has been our experience that increasing the dose may enable the medication to continue to be effective. It is important to understand that increasing the dose is an off-label use of this medication. It may increase the incidence of adverse reactions. When increasing the dose, we generally use generic finasteride 5mg that is taken whole or broken into parts (see Caution during Pregnancy).

Effects on PSA

Finasteride causes a decrease in serum PSA (prostate specific antigen) by approximately 50% in normal men. Since PSA levels are used to screen for prostate enlargement and prostate cancer, it is important that your personal physician is aware that you are taking Propecia (finasteride) so that he/she may take this into account when interpreting your PSA results.

Prostate Cancer Screening

The American Cancer Society and the American Urological Association recommend the following screening ages:

- Age 50 for men who are at average risk of prostate cancer and are expected to live at least 10 more years.
- Age 45 for men at high risk of developing prostate cancer: African American men and men who have a first-degree relative (father, brother, or son) diagnosed with prostate cancer younger than age 65.
- Age 40 for men at even higher risk (those with several first-degree relatives who had prostate cancer at an early age).
- Regardless of age, yearly screening for PSA level if 2.5ng/ml or higher, and every 2 years for less than 2.5ng/ml.

An evaluation should include a rectal examination, a PSA, and other tests that your examining physician feels are appropriate. The above are general guidelines recommended men regardless of whether they use finasteride or not. Specific recommendations for each patient should be based upon the judgment of his own physician.

Prescriptions

Your first prescription for PROPECIA (finasteride 1mg) will be for a 12-month supply (a 90-day Propak with 3 refills). You are encouraged to return to our office for follow-up evaluations. At each visit, you will be examined and any new information regarding finasteride and/or other therapies will be communicated to you. You will be responsible for obtaining urology evaluations if appropriate (see Prostate Cancer Screening). If you experience any problems or adverse reactions while taking finasteride, please contact us and/or your prescribing physician.

Please read Merck's Patient Information that comes with your medication.

I acknowledge that the doctor has the discussed with me the use and potential side effects of finasteride (Propecia, Proscar), as well as Post Finasteride Syndrome (PFS), and that all of my questions have been answered. I acknowledge receipt of the finasteride information sheet.

Please print:

_____ _____

Last Name First Name

_____ _____

Signature Date

Rose's Consent & Information on Finasteride and Propecia®

Paul Rose, MD, JD, Coral Gables, Florida, USA info@thehairlosscure.com

Patient Information PROPECIA (Pro-pee-sha) (finasteride) Tablets

Patient Name: _____ Date: _____

PROPECIA® is for use by MEN ONLY and should NOT be used by women or children.
Read this Patient Information before you start taking PROPECIA and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is PROPECIA?

PROPECIA is a prescription medicine used for the treatment of male pattern hair loss (androgenetic alopecia).
It is not known if PROPECIA works for a receding hairline on either side of and above your forehead (temporal area). PROPECIA is not for use by women and children.

Who should not take PROPECIA?
Do not take PROPECIA if you:

- are pregnant or may become pregnant. PROPECIA may harm your unborn baby.
- PROPECIA tablets are coated and will prevent contact with the medicine during handling, as long as the tablets are not broken or crushed. Females who are pregnant or who may become pregnant should not come in contact with broken or crushed PROPECIA tablets. If a pregnant woman comes in contact with crushed or broken PROPECIA tablets, wash the contact area right away with soap and water. If a woman who is pregnant comes into contact with the active ingredient in PROPECIA, a healthcare provider should be consulted.
- If a woman who is pregnant with a male baby swallows or comes in contact with the medicine in PROPECIA, the male baby may be born with sex organs that are not normal.
- are allergic to any of the ingredients in PROPECIA. See the end of this leaflet for a complete list of ingredients in PROPECIA.

What should I tell my healthcare provider before taking PROPECIA?
Before taking PROPECIA, tell your healthcare provider if you:

- have any other medical conditions, including problems with your prostate or liver

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.
Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take PROPECIA?

- Take PROPECIA exactly as your healthcare provider tells you to take it.
- You may take PROPECIA with or without food.
- If you forget to take PROPECIA, do not take an extra tablet. Just take the next tablet as usual.

PROPECIA will not work faster or better if you take it more than once a day.

What are the possible side effects of PROPECIA?

- Decrease in your blood Prostate Specific Antigen (PSA) levels. PROPECIA can affect a blood test called PSA (Prostate Specific Antigen) for the screening of prostate cancer. If you have a PSA test done you should tell your healthcare provider that you are taking PROPECIA because PROPECIA decreases PSA levels. Changes in PSA levels will need to be evaluated by your healthcare provider. Any increase in follow-up PSA levels from their lowest point may signal the presence of prostate cancer and should be evaluated, even if the test results are still within the normal range for men not taking PROPECIA. You should also tell your healthcare provider if you have not been taking PROPECIA as prescribed because this may affect the PSA test results. For more information, talk to your healthcare provider.
- There may be an increased risk of a more serious form of prostate cancer in men taking finasteride at 5 times the dose of PROPECIA.

The most common side effects of PROPECIA include:

- decrease in sex drive
- trouble getting or keeping an erection
- a decrease in the amount of semen

The following have been reported in general use with PROPECIA:

- breast tenderness and enlargement. Tell your healthcare provider about any changes in your breasts such as lumps, pain or nipple discharge.
- depression;
- decrease in sex drive that continued after stopping the medication;
- allergic reactions including rash, itching, hives and swelling of the lips, tongue, throat, and face;
- problems with ejaculation that continued after stopping medication;
- testicular pain;
- difficulty in achieving an erection that continued after stopping the medication;
- male infertility and/or poor quality of semen.
- in rare cases, male breast cancer.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of PROPECIA. For more information, ask your healthcare provider or pharmacist.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA1088.

How should I store PROPECIA?

- Store PROPECIA at room temperature between 59˚F to 86˚F (15˚C to 30˚C).
- Keep PROPECIA in a closed container and keep PROPECIA tablets dry (protect from moisture).

Keep PROPECIA and all medicines out of the reach of children.

General information about the safe and effective use of PROPECIA.

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information leaflet. Do not use PROPECIA for a condition for which it was not prescribed. Do not give PROPECIA to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about PROPECIA. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about PROPECIA that is written for health professionals. For more information, call 1-888-637-2522.

What are the ingredients in PROPECIA?

Active ingredient: finasteride. Inactive ingredients: lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, hydroxypropyl methylcellulose, hydroxypropyl cellulose, titanium dioxide, magnesium stearate, talc, docusate sodium, yellow ferric oxide, and red ferric oxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

For patent information: www.merck.com/product/patent/home.html

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I have read and fully understand the above information on Propecia and have had the opportunity to discuss it with the doctor prescribing it for me.

Signed: _____ Witness: _____

(Patient Signature)

Date: _____ Date: _____