

Hello Friends,



I am back! A lot has happened since my initial outreach – to the world and to me. This seems like a great time to share with you my progress and optimism. Please note this is merely an update – *not* an appeal.

Cutting to the chase ... my “fro” is back. My eyebrows are back. My eyelashes are back. My facial hair is back. Looking in the mirror is no longer a challenge. I like how I look; my self-confidence has been restored. For the first time, I have a girlfriend; three years ago, I would have thought this impossible. I went through high school with never identifying as he/him/his but, rather, as alopecian/alien-lookalike/freak.

It is not clear exactly what has caused my hair to regrow. It could be pharmaceutical intervention (I am on a JAK inhibitor, Xeljanz, and oral minoxidil). It could be the absence of certain stress events that accompanied me throughout high school. It could be environmental or other physiological factors. The answer is that I do not know; neither do my doctors. So ... I must appreciate what I have now, recognizing that it may not be permanent.

Without the anxiety and depression that accompanied the despair of my condition, I feel like a *completely* different person – in appearance, real-life, education, maturity, discipline, and focus. I started college (Wake Forest) this past fall, confident, ready, and excited to learn. I have thrived, which has coincided with the fact that it is the first time I have been able to fully focus on my academics (as opposed to alopecia). My enthusiasm for learning has grown as I have excelled. For example, I dove into both Russian language and Economics, and have spent my free time (during which I am not obsessing about my hair) geeking out and doing **extra** work. I have never had better grades. I am happy. I feel human. Feeling human feels great!

The National Alopecia Areata Foundation has been incredible, and I am so appreciative for their continued support and general awesomeness. Fellow alopecians I have met through NAAF have resulted in life-long relationships. Several weeks ago, my girlfriend, Caroline, and I had coffee with Bailey and her parents. Bailey was one of the special alopecia sufferers whom I met through NAAF in my early days after diagnosis. Even with little hair, she is exceptionally beautiful and allowed me to photograph her as part of my awareness-building series. In my original outreach, I shared this series with you. Bailey, like me, has had some hair regrowth. I think she would describe the psychological impacts very similarly



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to how I have. If you refer to my original series (<https://erniekaye.com/alopecia>), you will get more of the full before/after experience. It's pretty crazy to see the change. I assure you that the transition you see on the outside is multiplied by many times on the inside.

In terms of your previous support, I want to let you know that your donations have gone to excellent use. As you may recall, we were seeking to support the launch of NAAF's peer-to-peer mentoring program. This is a program through which experienced "alopecians" can help recently diagnosed kids who are suffering with their recent diagnoses. To date, NAAF's peer mentoring program represents 115 mentor-mentee relationships, and the number continues to rise. Not every kid will get their hair back; every journey is different. The hope is that through the mentoring program, each affected person will have a slightly better chance at developing coping mechanisms and a feeling that they are not alone.

Please see the below quote from a member of the NAAF community:

“*My 10-year-old granddaughter was diagnosed with alopecia areata when she was 2. The past few years have been very hard on her with her parents divorcing, moving, her mother remarrying and now the pandemic. The last few years she has lost her hair twice and gets so sad about it. I stand on the sidelines and try to help, but it wasn't until I attended a recent conference that I realized there was more out there that could help her. After attending the conference, I began to realize what a loving community NAAF was. I don't believe my granddaughter knows anyone that has alopecia and it could be so comforting...*

I want to thank you so much for your help with finding a mentor for my granddaughter. She really loves talking to her mentor Kayla and always has a smile on her face when she gets off FaceTime. I can't ever thank you enough.”

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At present, I have turned my focus to both the risk/reward profile – as well as the affordability – of Xeljanz, which is widely believed to be responsible for hair regrowth in a multitude of alopecia areata patients. The drug is experimental (i.e., not approved by the FDA) for my condition. On the risk front, I have been engaged in my own personal research project to ascertain how the risks of Xeljanz might impact my health later in life. On the affordability front, my incredibly patient and loving mother has been spending her time working with families who need support in accessing pharmaceutical payment assistance plans. With the help of some extremely generous friends in the biotechnology and medical community, I have put together the following report to better describe my conundrum.

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On September 1, 2021, the FDA issued a **black box warning label** on Pfizer's tofacitinib (Xeljanz) and, more broadly, across the entire class of Janus Kinase "JAK" inhibitors.

While this news certainly went unnoticed by almost every other college freshman, it was of utmost importance to me. The FDA's warning necessitated, for me, a very personal research project – a cost-benefit analysis of the increased cancer and cardiac risk versus the psycho-social benefit of keeping my hair. I went through high school with full-blast alopecia areata (marked by bald patches on my head, and complete absence of eyelashes, eyebrows, facial hair). It was a brutal experience, emotionally and socially, and I would have done anything to have changed my situation.

The introduction of Xeljanz into my life was a godsend. A well-established drug for Rheumatoid Arthritis ("RA"), Xeljanz has shown great initial promise in experimental studies for hair regrowth in patients with alopecia areata. It has worked very well for me, too; I entered my freshman year of college with a *normal* head and face full of hair. And, for the first time in years, I liked what I saw in the mirror.

Sadly, on September 1, we learned that Xeljanz carries major potential health risks – risks the FDA made clear that are too significant for me to ignore. Reality has presented me with a Hobson's Choice.

Xeljanz was first approved by the FDA in 2012 for patients with RA; since then, numerous other JAK inhibitors have either been developed in indications outside rheumatoid arthritis – generally in patients who are older and not in good health. Recently, given the unmet clinical need and prospects for corporate gain, the companies making these drugs have been pursuing them in dermatological conditions, including atopic dermatitis, psoriasis, and alopecia. However, JAK inhibitors have **not** been FDA-approved for use in dermatology.

As the FDA warning makes clear, Xeljanz comes with a multitude of potential risks: increased rate of blood clots, heart attacks, stroke, and various cancers (primarily lymphoma). Data from a post-marketing-approval study in Xeljanz was presented in 2021. The data demonstrated increased medical risks associated with chronic use of JAK inhibitors. In brief, the trial found that RA patients on Xeljanz had a 33% and 48% higher risk of heart attack/stroke, and malignancy, respectively, than an equivalent group of patients on standard-of-care therapy. Concerned, the FDA took the step of issuing guidance saying all JAKs should be considered to carry increased risks of heart attacks, strokes, and cancer. Key opinion leaders and doctors universally encourage alopecia areata patients to begin treatment with more benign drugs, as a means for preserving their long-term health. I have tried these drugs; they did not work for me.

To come to my own answer, I have read many peer-reviewed publications and have conferred with numerous key opinion leaders on the risk-reward of using Xeljanz in my situation. Included amongst those with whom I have spoken are research directors, pharmaceutical executives, doctors, and investors. I have met with luminaries from institutions like UC Irvine, Yale, Columbia, and Northwestern. I have been unable to find a consensus between the experts.

The field of alopecia therapies is evolving. For now, there is no clear answer; certainly, there is no "right" one. So, I must make decisions based on the information I have. In the absence of an obvious answer, I have asked each expert: "would you give this drug to your own child if they had what I have?" In almost every case, the answer has been affirmative; the psychological benefit of the therapy is deemed to outweigh the risks. So, I am going to continue taking the drug.

If I were seeking silver linings ... in the context of academia, I now have a much greater appreciation for the importance of research and its impact on real people in everyday life. In my case, the research has just begun.

Sincerely,



ERNIE KAYE

More 

A NOTE FROM Mom



Ernie's journey with alopecia has touched each of our family members, and NAAF has been with us for every step of the journey. We have enjoyed giving back to the community. Felix has participated as a volunteer at NAAF's annual conference, Mitchell has connected the organization with key opinion leaders and investors whom he knows from his professional life, and I have been involved in helping families gain access to Xeljanz.

As Ernie mentioned, Xeljanz is deemed as an experimental drug for alopecia, which means that anyone who is treated with Xeljanz is taking the drug "off label." While we can say with much certainty that the "experiment" is working, health insurance companies are not yet covering the cost of the drug for their clients. When used as prescribed, one may pay as little as \$20 a month for Xeljanz; however, the cost per month for off-label use is approximately \$5500. We know that some families who are desperate for Xeljanz have procured the drug from Canada (at a still exorbitant cost of approximately \$2400 per month). As you know, parents will do anything for their children. Pfizer offers assistance programs and a "coupon" for those who meet qualifying criteria, and programs are great, IF you can manage to get through all of the red tape.

In part because of my work as Founder of MedClaims Liaison, NAAF has connected me with other families who have faced difficulties in gaining access to Xeljanz at an affordable rate. It has been rewarding to be able to help other parents on effectively navigating how to affordably access a solution that can provide a sense of normalcy for their children.

A fellow parent and I are working on a "How To" guide for the process, and we are excited to be able to scale up our expertise so that more families have access to our knowledge.

We are all pleased that we are able to give back to an organization that has given so much to our family. And we thank all of you have been extremely generous with your hugs, kind words, shoulders to cry on, and the financial support that allows NAAF to remain a beacon of light for those who are going through a very dark and challenging time.