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# My Clinical Study Experience with Stage 4 Melanoma

**By Jamie Goldfarb**

I think of myself as someone who always looks on the bright side. Stage 4 cancer made me prove it.

I was born in Reading, Pennsylvania. After graduating from college in 1999, I moved to Washington, D.C. where I met my husband, Jeff, at a clinical research patient recruiting company. That's where I learned how important it is to get the clinical research story out to the public. We married in 2009 and have a son, Kai, age 7. I now work for a large public relations firm, preparing proposals for social behavioral public health projects.

Jeff, Kai and Jamie at the Empire State Building

I was born with a small birthmark on my left thigh. I never paid any attention until it started looking different, and then it took me a year to see my doctor about it. A dermatologist removed it with wide margins in January 2008. She diagnosed it as stage IIB melanoma, meaning no further disease was detected, and I went on about my life.

It healed fine but, over the course of the next year, I got multiple infections near the surgical site. My surgeon's office kept referring me back to my primary care physician to treat the infection. After the third infection, they decided to go in again to see if maybe they had left something behind, like a suture, that was causing infections. During that surgery, they found a mass of melanoma hidden in the deep tissue, which put me at stage III. During that surgery, they also did a wide excision, and a PET scan, which was clear. After consulting with my oncologist and a number of specialists, we decided not to go through with any treatment, so I went back to my normal life. That was December 2009.

In January 2010, I became pregnant. In October, I gave birth to our perfect baby, Kai. In January 2011, right before I was scheduled to return to work from maternity leave, my oncologist suggested that we do a follow-up scan, since we had not done once since the year before. That scan showed melanoma in my liver and my pancreas, which put me at stage 4.

At the time, there were only two approved treatments for melanoma. One was chemotherapy, but late-stage melanoma is highly resistant to chemotherapy. The other was high-dose Interleukin 2 (IL-2), but stage 4 melanoma has only about a 15% 5-year survival rate with that treatment. We had a brand new, 11-week old baby, so those odds weren't going to work for me.

When I was diagnosed, we were in a very fortunate life situation. At the time, my husband and I both worked for a company that did patient recruitment for clinical trials. That meant we had much more knowledge about medical research and clinical trials than most people. Also, we live near the National Institutes of Health.

Although there were only two approved treatments for melanoma, the research landscape was moving extremely quickly. There were several new, very promising treatments in

clinical trials (the majority of which are now approved treatments). Because late-stage melanoma is resistant to chemotherapy, the treatments are all different types of immunotherapy.

Before joining a trial, I had to pick the one that looked best. I also had to think about how that would affect my eligibility for the next one, and the next one after that. The potential side effects from the first trial can exclude you from the next one. For example, ipilimumab can cause colitis, which makes you ineligible for adaptive cell therapy. So, after I was diagnosed, it was a flurry of obtaining information, getting the opinions of melanoma specialists, and speaking with as many people as possible to determine what my treatment pathway would look like. We settled on an adoptive cell therapy clinical trial at the National Cancer Institute called TIL (for" tumor infiltrating lymphocytes").

The NCI branch that treats melanoma is the surgical branch, led by Dr. Stephen Rosenberg. Working with Dr. Rosenberg is a team of attending physicians that remains constant as a group but rotates in their patient duties every one to two months. Under them is a team of research fellows who rotate out each June. As a patient, your primary point of contact is your research fellow, but they make all treatment decisions as a group. We understood this structure when we went for our first screening appointment to find out if I would qualify for the trial. We took with us a picture of me and our baby. I asked my research fellow, Dr. Schaub, to take the picture with him to their group meeting, so everyone on the team could see what I needed to live for. I wanted everyone to know that, no matter what the side effects might be or the harshness of the treatment, I was determined to live for this new life I had just created. I had the responsibility to be there, to be sure my son had a mother and that my husband had a wife and partner. And, I wanted them to focus on the end game — survival – not on what I might have to go through to get there. After their meeting, Dr. Schaub called to tell me they had decided that I could join one of their TIL trials, and we scheduled surgery for the tumor on my liver.

The way TIL works is really awesome, in all senses of the word. First they harvest part of a tumor and extract all the white blood cells within that tumor, because those cells were able to identify and start attacking the tumor. They then replicate these cells in the lab by the billions. In my case, they genetically engineered the cells to express Interleukin 12 upon contact with tumor.

The cell-growing process takes about six weeks. While we were waiting, they decided to administer high-dose IL-2 to see what it would do against the cancer. IL-2 is a crazy, untargeted immunotherapy that works by eliciting a whole-body response. It revs up your immune systems and causes your white blood cells to go crazy. In the process, they might stumble upon and attack the tumors.

I went through an inpatient treatment for a week at a time, starting in January 2011. I did four dosing cycles over four weeks. When we checked in for the first round of dosing, we were in my room, taping pictures of Kai to the walls so I could see them from my bed. As we were doing this, the nurses kept coming in to say hello and introduce themselves. They knew our names and they knew about our baby. At first we were just very impressed by the customer service at this hospital, but after about the fourth time, we asked the nurse why everyone knew us and if that was normal. She told us that the doctors had taken the picture we had given Dr. Schaub of me and Kai and had walked it around the unit, saying, "This woman is checking in tomorrow and we are going to do everything we can to save her life." So we began our treatment journey with 100% confidence in our doctors' and our whole medical team's commitment to my survival.

IL-2 is insane. It causes full body rashes with extreme itching. The skin from my head to my shoulders cracked and peeled all four times. I gained 20 pounds of water weight within 24 hours each of the four times, despite copious nausea, vomiting and diarrhea. I hallucinated

deer in my room, hallways full of pink butterflies, antlers coming out of my doctors' head, full TV shows and movies complete with credits and commercials —while my eyes were closed and the TV was off — and math equations running across the walls. During one dose, my blood pressure dropped to 40/20, which caused my kidneys to start to shut down. I had horrible nightmares for more than a year.

My husband sat with me in the hospital every single day, sometimes staying overnight in the chair by my bed, while our parents tag-teamed caring for our new baby.

On our way home from the hospital one day, after my second in-patient treatment, we pulled onto our street. I was exhausted, feeling sick, and missing Kai. We were greeted by our entire street filled with signs. Every neighbor had a sign in their front yard that said "HOPE" next to a melanoma ribbon. They wanted us to know we were all in this together. And the IL-2 did work! It shrank the tumors in my liver and pancreas. Then, all of a sudden, my August scans showed about 35 new tumors, mostly under my skin.

Fortunately, the cells were ready, so they admitted me to the hospital in September for a month-long in-patient treatment. They first killed my current immune system with high-dose chemotherapy. When I was completely neutropenic, they administered the new cells and we waited for my cell counts to rise back up to safe levels so I could go home.

They injected the new cells mid-September. But then, scans from October through December showed the tumors were still growing. The doctors wanted to talk about next steps, but I wanted to give the treatment more time to be sure. We agreed to look at the scans in January and then decide.

In late December, I got a cold, which concerned me. Then, I felt the subcutaneous tumors shrinking. I thought that maybe the cold woke up my new cells.

My January scans showed the tumors were shrinking. It was working! From that point on, over the course of the next two years, my tumors kept shrinking until scans finally showed no evidence of disease.

The people at NIH were amazing. Dr. Rosenberg was in my room every day checking on me. He told me my cure was a miracle. I told him, "No, it's your life's work. You did it." Thanks to this amazingly complex immunotherapy, I have remained tumor-free for four years and I have no doubt I'll stay that way for another 50.

All Kai knows is that I used to be bald and took good medicine.

There are four things everyone who gets a serious disease should do: First, get yourself to a doctor who specializes in that disease and keeps up with current research. Second, do not treat clinical research as a last resort — consider it from day one. Third, don't forget it's *your* health at stake. Fourth, take advantage of advocacy group resources — I know the Melanoma Research Alliance (www.curemelanoma.org) does fantastic work.

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