Patient Sees Clinical Trial as Burdensome but Empowering

Cathy Fornabaio isn't the type to succumb to self-pity.

In 2001, Cathy was blindsided by a diagnosis of Behçet's disease, an autoimmune disorder that results from damage to blood vessels throughout the body.

Cathy went to bed on a Sunday night a healthy, 31-year-old working mother. When she woke up on Monday morning, she felt a painful heaviness in her chest.

Despite a trip to the doctor and a subsequent chest x-ray and a lung function test, both of which were normal, Cathy's pain worsened. By Friday night it had become so extreme that she ended up in the ER, where she was diagnosed with a heart attack. Doctors later changed their diagnosis and told her she hadn't suffered from a heart attack but from pericarditis, a condition in which the sac-like covering around the heart becomes inflamed—which had been brought on by lupus.

It was five months before Cathy learned that lupus was a false diagnosis as well and that she really suffered from Behçet's (pronounced Bish-ETTEs) disease, a rare, chronic, autoimmune condition that causes the blood vessels throughout the entire body to become inflamed.

Because Behçet's disease can involve blood vessels of nearly all sizes and types, it can manifest throughout the body including the eyes, mouth, skin, lungs, joints, brain, genitals, and GI tract.

Cathy struggled to continue with "life as normal" but soon had to quit her job as a fashion buyer. She endured debilitating headaches, aching joints, temporary vision loss, constant mouth ulcers and numerous other symptoms. It took all her strength to care for her young son: the simple task of making breakfast exhausted her. Still, she was determined to fight back. She started raising money for the American Behçet's Disease Association, volunteering from home.

Looking for Answers

Cathy's rheumatologist treated her with oral steroids; Solu-Medrol, a powerful IV steroid; and Cytoxan, a chemotherapy to suppress her overactive immunity, which was causing symptoms in her eyes and brain. But Cathy still struggled with her pain, and the powerful steroids were causing problems of their own: Cathy's bones were becoming weak, and she'd developed steroid-induced diabetes.

After two years, hobbling along on the regimen, she learned about Dr. Yusuf Yazici, a rheumatologist and associate director of the Seligman Center for Advanced Therapeutics at New York University Hospital for Joint Diseases.

"Dr. Yazici introduced me to clinical trials," she says. "I guess I looked at the clinical trials as hope. A lot of the medication I take is for rheumatoid arthritis or for lupus. I got excited because the trials were looking for something that was geared toward my symptoms."

Cathy admits she was nervous. To participate in the trial Cathy would have to stop taking the Solu-Medrol, Cytoxan, and any other immune suppressants. "With this disease if you let it flare up, the consequences can be irreversible, so going off my medicines was scary," she says. "I kept wondering: What if it doesn't work? What if it made me worse? When you take a medicine that has been around for 10 years you know it has helped some people. You don't get that sense of comfort in a clinical trial."

Cathy asked Dr. Yazici lots of questions and consulted every member of her medical team. She was terrified that if she went off her medications she might suffer another bout of pericarditis.

"I have a big team of doctors that includes a heart doctor, urologist,

eye doctor, rheumatologist, gastroenterologist, and endocrinologist," she explains. "I talked with every one of them before I went off my meds and joined the trial."

Cathy solicited input and support from her family as well. She knew that if she decided to participate, she'd need their help getting in and out of Brooklyn, where the trial was taking place. Her family was worried that neither she nor the researchers knew enough about the new medication, a tumor necrosis factor (TNF) inhibitor, but agreed to support her in her decision.

In the end, Cathy decided she had no choice but to participate. Standard therapy wasn't giving her the relief she craved and was causing too many problems. What's more, she felt like she needed to take action against her disease.

"One of the reasons I started volunteering with the ABDA was it was my way to fight back against the disease. I guess I felt the same way about clinical trials. I felt like it was my responsibility to myself and to others to do my part and fight back. I looked at it almost like a job."

To participate in the trial Cathy had to make biweekly trips into Brooklyn, a 75-minute drive from her home in Rockland County. Parking in the city was nearly impossible, so she'd often have a family member drive with her and stay in the car – circling the block or double parking when possible – while she went in for her appointments. The research staff was accommodating and friendly, but the hassle factor of getting in and out of the city, particularly on days when she felt her worst, was high. Cathy

admits that, had she not begun to experience positive results after only a few weeks, she might have been tempted to drop out of the six-month study.

"I can't imagine what it would have been like to stick with it if I wasn't getting relief," she says. "That's was what kept me going. I knew it was helping me."

Every two weeks Cathy visited the clinic, where she would be given an injection in her abdomen. Staff would draw blood and Cathy would fill out a questionnaire about how she was feeling. Although the shot hurt, Cathy says she didn't suffer any side effects.

Within six weeks of joining the trial, Cathy started feeling better.

"Because of my joint pain it's very hard for me to walk down the block or up stairs," she says. "But I suddenly noticed that it wasn't so painful. My hands weren't hurting as much either, and I had more strength. About two days after a shot I'd feel better but by day 12 I'd start hurting again, so I could tell the drug was working."

The trial drug Cathy took was approved by the FDA in December 2002 for rheumatoid arthritis and is now marketed by Abbott Laboratories under the name Humira. Although Humira gave Cathy relief from her Behçet's symptoms, her current insurance prescription coverage doesn't cover injectable drugs so she is once again dependent on Cytoxan and Solu-Medrol, as well as pain medication, which she takes twice a day.

Cathy still struggles with her disease. Every few months she'll have a bout of pericarditis, and she's lost nearly all her vision in one eye on several occasions. She'd love to participate in another trial, she says, but there aren't many trials for Behçet's and she hasn't been able to find one near her home.

"Participating in a clinical trial was scary and a pain in the neck," she says, "But it worked. In the end for me it was a blessing."

While she encourages others to get involved in clinical trials, she always underscores the need for commitment: participating can be burdensome, but it is empowering.

"Everybody can sit around and complain," she says. "But if we all do a little bit, there is power in numbers. If we all do our part, we can get so much further and we may have an answer in the end." ■

This story is from a series of articles created by CISCRP as part of their educational awareness campaign to increase public understanding that those who volunteer to participate in clinical trials are genuine "Medical Heroes."