



# How I Learned the Hard Way to Ask Questions About Medications

By Rachel Brummert

WHAT SHOULD one consider when prescribed a new medication. Is the medication appropriate for the illness? Will it work? Will I have an adverse reaction? These are things I never thought about before I had an adverse reaction to an antibiotic. I was so trusting that my doctor knew best. Once I learned more about the process, I became an accidental advocate for asking questions of my doctors before I agreed to a prescription.

## Background story

In 2006, I had a cough that I couldn't shake. I went to my doctor with the hope that she would prescribe something that would make my annoying cough go away and I'd be feeling better soon. When Dr. Hughes walked into the exam room, she listened to my lungs, looked in my nose and throat and in her friendly manner explained that I was congested, but nothing jumped out at her.

"I'll do a swab and give you an antibiotic just to be safe. It couldn't hurt," she said. She thought it might have been a sinus infection and prescribed me an antibiotic called Levaquin. I took the Levaquin as prescribed for 2 weeks.

A month later, I was running errands. The pharmacy, ironically the same one I picked up the Levaquin from, was my last stop. I was not in a good mood and wanted to get home. It was

about to rain and the sky looked as angry as I was. I get cranky when I'm in pain. Leaving the pharmacy, I was relieved to be heading home to get some rest and eat some soup. As I stepped off the curb and walked to my car a few feet away, I felt the worst pain of my life. My foot popped, then went limp and I fell to the ground, unable to move it. I could have sworn someone kicked me in the back of my foot; only no one was around. I felt confused, not understanding what was happening to me. All I was doing was walking.

What happened was my Achilles tendon in my right foot ruptured and balled up in my calf. It's as gruesome as you are imagining. My surgeon at Reconstructive Orthopedics in South Jersey had to sew my tendon back together in my right foot.

As I was rehabilitating from the surgery, I ruptured my Achilles tendon in my other foot, the left one. I couldn't believe this was happening. So again, I went through the same surgery, the same physical therapy, and same medical bills. This had to be the end of it, right? Not even close. Soon after, I ruptured the tendon again in my left foot, this time above the previous surgery site. I went through three Achilles tendon surgeries in a little over a year and a half.

For some time during and after these episodes, I asked, "why me?" My surgeon was also baffled, and he decided to review my medical history to see if something was causing these tears. Clearly, these events are unusual for someone my age to experience in the normal course of life..

I told him I rarely get sick but off-handedly mentioned I had a suspected sinus infection a month before I ruptured the first time. His eyebrow raised and he asked what I was prescribed for it. When I told him it was Levaquin, he put his pen down and leaned against the exam table. He began to tell me that Levaquin (levofloxacin)- and other fluoroquinolone antibiotics such as Cipro (ciprofloxacin) and Avelox (moxifloxacin) can cause tendon ruptures and other ailments. He added that in 2008, the U.S. Food and Drug Administration added a Black Box warning to fluoroquinolone packaging stating that they can cause tendinitis and tendon ruptures. Unfortunately, this warning came out two years after I was prescribed Levaquin.

Could this have been prevented? Why was I so impacted by this one medication, while other patients were not?

Pharmacogenomics is an emerging field which studies how your DNA affects the way you respond to medications. In some cases, your DNA can affect whether you have a bad reaction to a drug, whether a drug can help you, or whether it has no effect at all. For example, it can determine how fast or slowly your body absorbs the drug. It can determine what

receptors you have and how many, which can affect your response to a drug.

The good news is that genomic testing is available and can show gene variants which may determine how your body reacts to a drug. A group of harmed patients advocates long ago figured out that response to fluoroquinolone could have a genetic component, resulting in a toxic effect. These advocates were using genetic testing company 23 and Me to see which genetic variants may play a role in drug response. While the damage had already been done, I decided to take the test for my own information.

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I was excited when my test kit came, believing the vial full of my spit could provide more information as to how this could have happened. My raw results showed that I had the C677T variant of the methylenetetrahydrofolate reductase (MTHFR) gene. This is a common gene variant in those who suffer from what the Food and Drug Administration coined as Fluoroquinolone Associated Disability (FQAD), also known as Fluoroquinolone Toxicity. The variant does not metabolize the drug properly and subsequently results in toxic buildup products since the body cannot detoxify them. It is now 16 years since I took Levaquin. To date, I have had over 30 tendon ruptures, all of which required surgery. I am resigned to the fact that this could be a life-long condition.


Due to the effects of Levaquin, I went from having a cough to becoming disabled. I often wonder if I had been genetically tested before taking the medication, would that data have helped me and my doctor make an informed decision about the best course of action. Or whether something else could have been tailored to my specific needs and conditions. A key question here, though, is how could I as a patient have known about pharmacogenomics?

Since then, I have devoted my life to patient safety and patient awareness. I chose to work with the American Society of Pharmacovigilance, and in the field of pharmacogenomics. I found out the

hard way that it is important to work as a team with your doctor and to ask questions about why a particular drug is being prescribed. Is it appropriate for the condition? Are there other options to exhaust first? Is it being prescribed off-label? Can a test confirm a diagnosis before I start taking medication for it?

All of this matters. As it turned out, my swab to test for infection at the start of all this came back 5 days later. It turned out I never had an infection in the first place. By then, I had already started Levaquin and the damage had already been done.

Sometimes the cure is worse than the illness. Annually, adverse drug events account for one million emergency room visits, 2.2 million hospitalizations, 3.5 million physician visits, and a staggering \$136 billion in healthcare costs. Adverse drug reactions are also the fourth leading cause of death in the United States.

My mission is to change that. 



### Rachel Brummert

Rachel serves as a Special Government Employee (SGE) at the U.S. Food and Drug Administration and a contributor at Drugwatch and Medshadow Foundation. She is also a collaborator at the Centers for Disease Control and Prevention (CDC) and a nationally known patient advocate. Her experience with an adverse drug reaction from a commonly prescribed antibiotic led her to the field of patient safety, pharmacovigilance, and pharmacogenomics.

Rachel uses her experience as a harmed patient to advocate for others and works in partnership with established consumer advocacy groups and agencies whose work centers around patient safety. Her mission is to turn pain into purpose.

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