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Perez, Thomas

From: Bud |
Sent: Friday, April 12, 2002 12:03 AM
To: perez@cdcr.fda.gov
Subject: Advisory Committee Meeting

What follows is a statement I would like to be distributed to those attending the April 23rd Advisory Committee Meeting if at all possible:

Dear Advisory Committee Meeting Members;

This is about Lotronex.

I want to offer you a different perspective than most others have. It is not me that suffers from IBS It's my wife of 39 years. In September of 1999, IBS took control of her life. We married in our teens. Through the years, we've been blessed beyond belief. And through these years, she (Sharyn) has been the perfect model of a wife, friend and mother as an asset to the community . A classy woman, always smiling and full of life. A social butterfly if you will, always ready to help someone Always there for her friends, family and strangers on the street. Always, so upbeat and caring. Giving so much and asking so little.

In September of 1999 that all changed with the onset of IBS. It hit her hard stealing probably 75% of her quality of life. You see, her IBS is in that 5% severity range. Yes, the diarrhea is terrible with the "daily" uncontrollable and explosive episodes, the accidents and the need to know where every public and non-public restroom is located in our community, but she would gladly accept coping with it if the pain would go away. She has abdominal pain 24 hours a day and there has not been one day without pain since her IBS began. Most of the time it's what she calls, "low rumbles with spikes" and these periods are bearable. But, the other 40%, or so, of the time involves debilitating gut pain that at times will put her in the fetal position for hours and even days holding her gut and praying for relief with vicodin doing little if any good. I have seen her fall to the ground many times because the pain was overwhelming. And, each night when we sit down for dinner she knows she must eat and she knows she will pay for it five out of seven nights with cramps. She is usually cramping before she finishes dinner. In fact, a glass of water will sometimes set the cramps off.

Her IBS is destroying both our lives. Our social life is gone as is her smile. Vacations aren't desirable anymore. My heart cries for her each evening and the many days when I see her cramping The expressions of pain on her face. There's been times when I've left for work only to turn around at the halfway point, going home with tears in my eyes to be with her. She gave up her work, because she couldn't work. And, there's much more, but suffice to say: There's a black cloud over our home and it's been here for two and a half years.

She's tried the gamete of meds and herbals as well as acupuncture, hypnosis and counseling. She's even tried illegal narcotics. The only thing that's helped is Lotronex. Its effect was immediate and it restored at least 50% of her quality of life and mine as well, but that relief was short-lived as it was taken away from her.

We know she will most likely have IBS for the rest of her life, which will most likely mean a shortening of life for her and probably me (depression does that). We also know the pros and cons of Lotronex usage far better than most IBSers. We both agree the risk versus reward ratio unquestionably dictates that Lotronex is the only choice if it comes back.

As a closing thought, if she were a pet, loved by her owners, she would have been put to sleep by now. Please do all in your power to help Lotronex get back on the shelves.

Thank you Bud & Sharyn Hodorowski