



FDA DRUG ADVISORY COMMITTEE MEETING - APRIL 23, 2002
(Submitted by: Maria Zargo)

My name is Maria Zargo. I'm from Brookfield, Connecticut. I am a LAG Coordinator, but I am here representing myself and some who were unable to attend this meeting. I am a wife, mother, former career woman and I suffer from severe IBS. Most recently I was forced to resign my position with a prestigious Fortune 500 company. I was no longer able to make the 45-minute commute to work every day without stopping at a supermarket to use the restroom. My work life, my family life and my independence had been permanently compromised until Lotronex came along.

I had been on a reduced dosage of Lotronex for nearly two years without side effects. I am living proof that this drug is extremely effective and very safe when used correctly and at the proper dosage. As with any other medication on the market, dosage administration should not be considered a "one-size fits all" scenario. Your risk management debacle could be solved if you would only adhere to this advice, advice given by those who are the true experts – the users of Lotronex.

All drugs have side effects; and knowing what we know about the risk/benefit ratio of Lotronex, we are willing to accept those risks. The majority of us have expressed a willingness to sign a waiver if need be, as is currently being done with other drugs, but that was never even presented to us as an option. Nor have we been given the option of a truly viable compassionate use type program that doctors would be willing to endorse. With Zelnorm's rejection and Cilansetron's approval being questioned, one can only presume that this continues to be politics as usual and not at all about science and patient needs.

It would be easier to have ailments like migraine headaches or IBD because there are effective treatments on the market, and public perception is one of understanding and sympathy. Today, IBS sufferers have no viable alternative medication that works. Lotronex continues to be the only drug ever prescribed that has significantly improved or completely eliminated the horrible, debilitating symptoms of diarrhea predominant IBS.

For those who continue to view IBS as nothing more than a "vexing inconvenience," we hope that the information we provide you with today will change that view. Being hospitalized for dehydration caused by IBS is more than an inconvenience. Stories of suicide attempts attributed to IBS suffering cannot be ignored. Missing out on life's simple pleasures like attending your child's sporting events is downright depressing, and it affects everyone in the family. It goes beyond a quality of life issue. Being afraid to leave your home for extended periods of time for fear of embarrassing incontinence, is humiliating and not a mere inconvenience. The cramping and pain, the exhausting, numerous trips to the bathroom, the inability to eat healthy, nutritious foods, can be intolerable

FDA Advisory Committee Meeting – April 23, 2002
Page 2

and not just an inconvenience. Job loss and family stress are undeniable and commonplace. So I'm hoping that you can understand why I take offense when someone refers to my condition as a mere inconvenience.

IBS continues to be poorly understood. Even today there are some doctors who are truly misinformed referring to it as "bathroom anxiety." Because of these misconceptions and lack of information, many patients are misdiagnosed with "mental health" problems and are given unfair labeling and treatment. For this reason, the treatments and medications that have been prescribed over the years have fallen far short of success. I have attached a list of prescription drugs and herbal remedies that patients have tried over the years with little benefit if at all. This list should have been distributed to you.

The bottom line is, sure there are alternate IBS treatments on the market today. What some refuse to understand is "THEY DON'T WORK." We are being subjected to experimenting with dangerous, addictive drugs like codeine, Vicodin and Oxycontin that have a much higher risk factor than Lotronex and do not contain the benefits that Lotronex provides. The FDA worries about the risks associated with Lotronex? What about the side effects and toxicity we're exposed to by taking these other drugs? I'd say taking Oxycontin, Vicodin or Codeine every day poses a very high risk of addiction if nothing else, which presents a whole set of other problems for the patient.

There is one other drug that I have purposely not listed for fear that certain parties may try to sabotage its access as well. This drug made it possible for me to travel to Bethesda and speak before you today. I only mention this because this drug is chemically related to Lotronex, yet it is not approved for IBS use, although it should be, and is extremely expensive. Like Lotronex, it works on the same 5HT3 receptors in the gut, and it is NOT an antidepressant. It has proven significantly superior over the other remedies I have attached and, again, ONLY because it's chemically related to Lotronex. I am extremely thankful that I was made aware of this medication, or I would have returned to my non-functional lifestyle once again.

In this great country of ours, we often hear the words "freedom of choice." On November 28, 2000 that freedom of choice was taken away from us. For many on Lotronex, it was the first time in years that living a "normal" life was possible. A life that so many take for granted.

Finally, please return Lotronex to those of us who so desperately need it. We depend on it, our families depend on it. Please keep the patients' needs at the

FDA Advisory Committee Meeting – April 23, 2002
Page 3

forefront and put money and politics aside. By continually denying us this right to Lotronex, the long-term repercussions will be catastrophic and future IBS drug research will be kept on the back burner. Our fate is in your hands.

Thank you.

(Attachments to follow)

ATTACHMENT – PAGE ONE

“MAGIC COOKIES AND OTHER INEFFECTIVE IBS D REMEDIES”

**ACCUPUNCTURE
ACIDOPHILUS
ALFALFA
ALKA SELTZER
ALOE VERA
AMITRIPTYLINE
ANTIBIOTICS
ATIVAN
BEANO
BENEDRYL
BENTYL
BIOFEEDBACK
BUSPAR
CALTRATE D
CHARCOAL TABS
CHOLESTYRAMINE
CITRUCEL
COCONUT MACARON COOKIES
CODEINE
DESIPRAMINE
DICYCLOMINE
DONNATOL
DONNAZYME
DOXEPIN
EFFEXOR
EQUALACTIN
GAS X
GINGER
HOMEOPATHY
HYPNOSIS
IBSACOL
IMIPRAMINE
IMMODIUM (Large quantities of Immodium – e.g., 8 pills per day.)
IRON
KAOPECTATE
LACTAID
LEVBID
LEVSIN
LIBRAX
LOMOTIL**

ATTACHMENT – PAGE TWO

“MAGIC COOKIES AND OTHER INEFFECTIVE IBS D REMEDIES”

**MARIJUANA
METAMUCIL
MYLANTA
OREGANO OIL
OXIDATIVE THERAPY (Which is a diluted solution of hydrogen peroxide
fed intravenously over a period of one hour or more. Very uncomfortable.)
OXYCONTIN
PAMINE
PAPAYA ENZYMES
PAREGORIC (TINCTURE OF OPIUM)
PAXIL
PEPPERMINT PILLS
PEPPERMINT TEA
PEPTO BISMOL
PROBIOTICS
PROZAC
PSYCHOTHERAPY
RASPBERRY LEAVES
REGLAN
REMERON
RF PLUS WITH BISMUTH
ROBINOL FORTE
SEA CURE
SHARK CARTILEDGE
SIMETHICONE
SLIPPERY ELM
VICODIN
WELLBUTRIN
XANAX
ZOLOFT**