

FDA Advisory Committee Meeting for the NDA for Zelnorm and Chronic Constipation – July 14, 2004

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I am here today representing patients and sufferers. I have paid all my own expenses to be here.

Members of the Committee, thank you for the opportunity to appear before you. I am the President and Founder of the Irritable Bowel Syndrome Self Help and Support Group and founder of the Zelnorm Action Group.

The 10,000 member Irritable Bowel Syndrome Self Help Group has endeavored, since 1987, to educate and provide support for people who have functional gastrointestinal disorders and to encourage both medical and pharmaceutical research to make our lives easier via our successful internet website for sufferers.

I have been a sufferer of diarrhea-predominant Irritable Bowel Syndrome for over 25 years. Much like chronic constipated individuals, there are challenges that I face each and every day in order to cope with my functional gastrointestinal disorder. It affects my family's lives, my career and I am constantly reminded of my own physical limitations because of this very burdensome illness. Today I have the support of the members of the Zelnorm Action Group, Irritable Bowel Syndrome Self Help and Support Group and Irritable Bowel Syndrome Association. I am privileged to act as the representative today for all those members who were too ill to travel here today. I would like to also acknowledge all their efforts to date.

Functional constipation is a common problem in our community with its prevalence ranging from 2% to 28%. Its diagnosis is made by careful delineation of its duration and characteristics. Constipation classification into subtypes results in overlapping symptoms and blurring between the subtypes. The distinction between IBS with constipation and functional constipation is important as the focus in treating functional constipation is to improve bowel habits alone. In an IBS patient, abdominal pain and other symptoms must also be addressed. Most chronically constipated patients do not require diagnostic studies beyond a careful history and physical examination. For clarification purposes, my

presentation today refers to individuals with only functional constipation lasting longer than 6-months and widely given the name of chronic constipation.

As I am a focus in the community for information about functional gastrointestinal disorders, I communicate with a great many people who have run out of options. They do not know where to turn and their quality of life has greatly suffered. Many current approaches to chronic constipation, including the use of fiber, osmotic and stimulant laxatives, biofeedback training, and surgery, often fail to control the patient's symptoms adequately, produce problematic side effects, or lose effectiveness with time. Most available and approved drugs for constipation have been passed down from antiquity and have not been tested in modern, well-designed studies. Primary care physicians and the sufferer believe there are very few other options available to them because chronic constipation is not usually viewed of clinical importance until it causes physical risks or impairs quality of life. Physicians often prescribe drugs for constipation with which they are familiar and comfortable, and in most cases anything will do.

Chronic constipation is a very unpleasant disorder and in some cases individuals who suffer from chronic constipation do not have a bowel movement for up to 21 days. Their quality of life is greatly diminished by this basic impaired function that most individuals take for granted. They may pass hard stools, lack the ability to defecate on demand or strain at every bowel movement.

I am here today to tell you that chronic constipation is a condition which cries out for more attention. It demands the continued use of a medication, Zelnorm, already proven in the treatment of functional constipation and IBS-predominant constipation. This committee must provide clear indication to the medical community that Zelnorm should additionally be made available for the indication of chronic constipation without any further burden to the physician or patient in prescribing this medication or getting access to this medication respectively.

As with Lotronex, a drug with the opposite effect of Zelnorm, ie: for severe functional diarrhea individuals, this committee listened to myself and others from the Lotronex Action Group in April 2002, make presentations as to how difficult it is to live with a gastrointestinal disorder. Although many of us do now have access to Lotronex, we are challenged by physicians who lack the knowledge or who are fearful of prescribing a medication because of a negative message about its use.

Zelnorm has an admirable safety record in clinical trials and general use. Its virtues should be celebrated and not limited in its usefulness as a medication to ease the suffering of a chronic constipation individual.

An electronic survey was recently conducted by the Zelnorm Action Group. Individuals were screened so that results were recorded only for those prescribed Zelnorm after indicating their symptoms of chronic constipation to their primary care physician.

While taking Zelnorm, chronic constipation sufferers report a quality of life that is dramatically better.

79% of those surveyed indicated that they had no significant side effects at all.

The Zelnorm Action Group is prepared to place educational information about Zelnorm on their website in order to reach out to the chronic constipation community. This provides an effective forum for educating chronic constipation sufferers about Zelnorm's proper use.

In conclusion, the quality of life of constipation sufferers was dramatically improved with access to Zelnorm. The medical community should be informed that a treatment is available which will improve the patient's outlook. Adverse events should not deter either the pharmaceutical or the FDA from maintaining the drug's availability.

Zelnorm has a place as an effective treatment for chronic constipation sufferers and should be indicated as such to the patient and medical community.