

**FDA Gastrointestinal Drugs Advisory Committee NDA for Prucalopride
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Members of the Committee, thank you again for the opportunity to appear before you. I am the Founder of the IBS Patient Group. My name is Jeffrey Roberts and I am the Founder of the IBS Patient Group. I am here today representing patients and sufferers. I have paid all my own expenses to be here.

The IBS Patient Group has endeavored, since 1987, to educate and provide support for hundreds of thousands of people who have functional gastrointestinal disorders, or FGID's, and to encourage both medical and pharmaceutical research to make our lives easier via patient advocacy efforts. I have provided testimony to this committee several times.

I have been a sufferer of an FGID, namely IBS, for over 25 years. I face challenges each and every day in order to cope with my illness. It affects my family's lives, my career and I am constantly reminded of my own physical limitations because of this very burdensome illness.

Functional constipation is a common problem in our FGID community with its prevalence ranging from 2% to 28%.

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 traditional 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, they produce problematic side effects, or lose effectiveness with time. Newly approved drugs for constipation have been successful for some patients; however, they haven't quite met the needs of the majority. Physicians often prescribe medications for constipation with which they are familiar and comfortable, and in most cases, anything will do.

However, chronic constipation is a very unpleasant disorder and in some cases individuals who suffer from chronic constipation may not have a satisfactory 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. Noelle, a member of the IBS Patient Group, says, **"People who don't deal with chronic constipation have no concept of how it can destroy your life, personal relationships, brain health and ability to work - it's an absolutely miserable problem that affects all other areas of your health."**

While Zelnorm, a medication for Chronic Idiopathic Constipation and IBS-C, met the needs of many patients, its removal from the market in 2007 created a gap in treatment options until new treatment options were approved in the subsequent years. Prucalopride, the same class as Zelnorm, but with the distinction of a diminished risk of cardiovascular issues and a favorable safety profile, has proven to be a successful treatment option by patients and physicians in other countries. **Physicians are well-versed at-risk management and, along with patients are risk-adverse. Prucalopride meets this goal as another treatment option.**

There is strong evidence that chronic constipation presents itself more frequently in women versus men and its prevalence increases with age. The subjective perception of chronic constipation at times leads to disagreements with physicians and patients as to whether someone is actually suffering from constipation. This leads to minimizing the illness and a vicious cycle of over the counter remedies of limited efficacy versus medications like Prucalopride which are more suited to treat this illness.

Traditionally FGID's were not considered to be associated with an increased risk of mortality; however, recent studies have shown that there is a risk from constipation. Having personally experienced a sudden episode of severe impacted constipation with life threatening consequences, I can relate to the anguish that a chronic constipation sufferer has to deal with on a near constant basis. Given the fact that constipation occurs more frequently in the elderly patients and that life expectancy is increasing, we can likely expect an increase in the prevalence of constipation in the years to come along with quality of life issues unless more patients are taken seriously and offered a chronic constipation medication like Prucalopride. The IBS Patient Group is prepared to place educational information about Prucalopride on their website in order to reach out to the chronic constipation community. This provides an effective forum for educating constipation sufferers about Prucalopride.

In conclusion, the quality of life of constipation sufferers was dramatically improved with access to Prucalopride in other countries. The medical community should be informed that a new treatment option is available which will improve their patient's outlook. Prucalopride has a place as an effective treatment for chronic constipation sufferers and should be approved and indicated as such to the patient and medical community.

Thank you.