FDA Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Meeting sNDA for Zelnorm
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Members of the Committee, thank you for the opportunity to appear before you. I am the Founder of the IBS Patient Group. 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 IBS and to encourage both medical and pharmaceutical research to make our lives easier via our IBS patient advocacy efforts.

To IBS patients, IBS with constipation is not a benign illness. The burden on their quality of life along with their families' lives is enormous. IBS with constipation cannot be managed simply by diet alone, by a lifestyle change or by doing more exercise. Enough research has been completed in the last several decades that clearly illustrate that the quality of life of an IBS sufferer is lonely, burdensome and there remain unmet needs for relief that are needed.

Menno, a member of the IBS Patient Group, describes his life with IBS with constipation as if he was **"Living in a cage, with a door that isn't locked, but you are unable to open the door. Your mind is telling you what you could do, and your body is constantly telling you: no, you cannot."** Karen says it is as if she is **"Living in her own world as no one really understands the pains we go through. Housebound, loss of friends, activities, loneliness, and depression."**

I have provided testimony to this committee several times. In 2004 I testified that IBS sufferers reported that while taking Zelnorm they felt a near complete cessation of their symptoms and it changed their lives for the better.

Following the withdrawal of Zelnorm from the market in 2007, I was flooded by messages from former Zelnorm users who were desperate for access to the medication. While we are very grateful that industry and the FDA have developed and approved some new IBS with constipation medications since 2007, some of those original Zelnorm users are still desperate for access to Zelnorm.

58% of IBS Sufferers surveyed by the IBS Patient Group over the month of September 2018, indicated that their quality of life is greatly impacted by IBS. 91% surveyed indicated they have used a medication to try and treat their IBS symptoms.

Our survey also indicates that **IBS sufferers are prepared to accept risks related to treatments for IBS.** The trend for their risk tolerance is between a serious side effect from a medication and a low risk of a side effect from a medication. **Only 8% said that it was acceptable to have no risk while taking a medication.**

It is not a new finding that IBS sufferers are prepared to accept risks related to the use of effective treatments for IBS. Patients are well versed at risk management and are asked to make risk decisions every day and are comfortable doing so_if adequate information is made available to them by their physicians. We believe patients are interested in participating in programs to better identify risks related to the use of treatments, and to work with the FDA to reduce those risks as much as possible. The IBS Patient Group is prepared to place educational information about Zelnorm on their website in order to reach out to the IBS community. This provides an effective forum for educating IBS-C sufferers about Zelnorm's proper use.

In 2007, we felt that removing access for Zelnorm further burdened patients and doctors and that the FDA pulled the medication from the market too quickly. Since Lotronex, for IBS with diarrhea patients, came back to the market in 2002 under a restricted access program, we have observed a positive safety record for patients and access restrictions being lessened over time; however, Lotronex has been lightly prescribed notwithstanding the benefit outweighing risks for appropriate patients. We do not want Zelnorm to also become lightly prescribed where, from its history, patients reported a near cessation of their IBS-C symptoms when it was first marketed. We believe that the re-approval of Zelnorm to manage IBS-C symptoms will provide further access to a treatment option where other new treatments have not sufficiently met patients' needs. Physicians and patients need options, and the more options that are available the greater likelihood that patients' symptoms can be effectively managed. Noelle a former Zelnorm user and member of the IBS Patient Group says, **"I have classic IBS-C and while using Zelnorm it was the first time in my life that I felt normal and my gut acted the way it should. To say it was life altering was no exaggeration. I had a normal life without complications of any kind. I was absolutely stunned at how lovely it was to simply have a working gut."**

In conclusion, IBS sufferers' quality of life was dramatically improved with access to Zelnorm. IBS sufferers are prepared to accept risks associated with any medication and want to work with the FDA to reduce those risks, but without the burden of access restrictions. **We believe Zelnorm to be safe and that the benefits of Zelnorm outweigh the potential risk for adverse side effects if prescribed properly.**

As an IBS sufferer for over 25 years, the challenges that I face are far more significant than the small risk of a cardiovascular adverse side effect from Zelnorm.

Thank you.