FDA Advisory Committee for Zelnorm

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Prevalence of Chronic Constipation

References: Definitions, Epidemiology, and Impact of Chronic Constipation, Nicholas J. Talley, MD, PhD, FRACP, Vol. 4 Suppl. 2 2004 Reviews In Gastroenterological Disorders
How does a Chronic Constipated sufferer feel?

- Unwell
- Alone
- Worried
- Frustrated
- Desperate
- Helpless
- Poor quality of life
What are the symptoms?

- May not have a bowel movement for up to 21 days
- Pass hard stools
- Lack the ability to defecate on demand
- Strain at every bowel movement
Quality of Life with Zelnorm

Side Effects while taking Zelnorm

- **Diarrhea**: 16%
- **Rectal Bleeding**: 5%
- **Ischemic Colitis**: 0%
- **Nothing Significant**: 79%
- **None**: 79%

**Patients’ Perspective**

**References:** Electronic survey conducted by the Irritable Bowel Syndrome Self Help Group June 2004 – July 2004 of some current Zelnorm users.
Conclusion

• Chronic constipation sufferer’s quality of life is dramatically improved with access to Zelnorm.

• Adverse events should not deter either the pharmaceutical or the FDA from maintaining the drugs availability.

• The medical community must be informed through an additional indication that Zelnorm is an effective treatment for chronic constipation.