

**Citizen Petition from Hyman, Phelps & McNamara, P.C. for Zelnorm  
Docket #FDA-2018-P-4490  
November 21, 2018**

**Comment by Jeffrey D. Roberts, MEd, BSc on February 1, 2019  
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I am the Founder of the IBS Patient Support Group. The IBS Patient Support 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.

We testified to the FDA about Zelnorm in 2004 as well as in 2018 in part illustrating that the quality of life of an IBS sufferer with constipation is lonely, burdensome and there remain unmet needs for relief that are needed. In 2004, we 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. We stated that IBS sufferers are prepared to accept risks related to 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. In 2007, we felt that removing access for Zelnorm from the market burdened patients and doctors and that further delaying its re-introduction to the market with cause further hardship.

We feel that the Citizen Petition presented from Hyman, Phelps & McNamara, P.C. after the FDA Gastrointestinal Drugs Advisory Committee on October 17, 2018 to discuss the reintroduction of Zelnorm (tegaserod) for Irritable Bowel Syndrome with constipation (IBS-C), is without merit or substance. Holding up access to a medically significant medication for IBS patient relief is burdensome and unnecessary. We urge the FDA to respond as quickly as possible and complete their decision, following on the recommendation of a positive decision by the FDA Gastrointestinal Drugs Advisory Committee on October 17, 2018 to re-approve Zelnorm.

Thank you,

Jeffrey D. Roberts, BSc, MEd  
Founder, IBS Patient Support Group  
<https://www.ibspatient.org>