

FDA  
Advisory  
Committee  
for sNDA for  
ZELNORM

Docket #FDA-2018-N-3223

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# What is the burden of living with Irritable Bowel Syndrome with Constipation (IBS-C)?

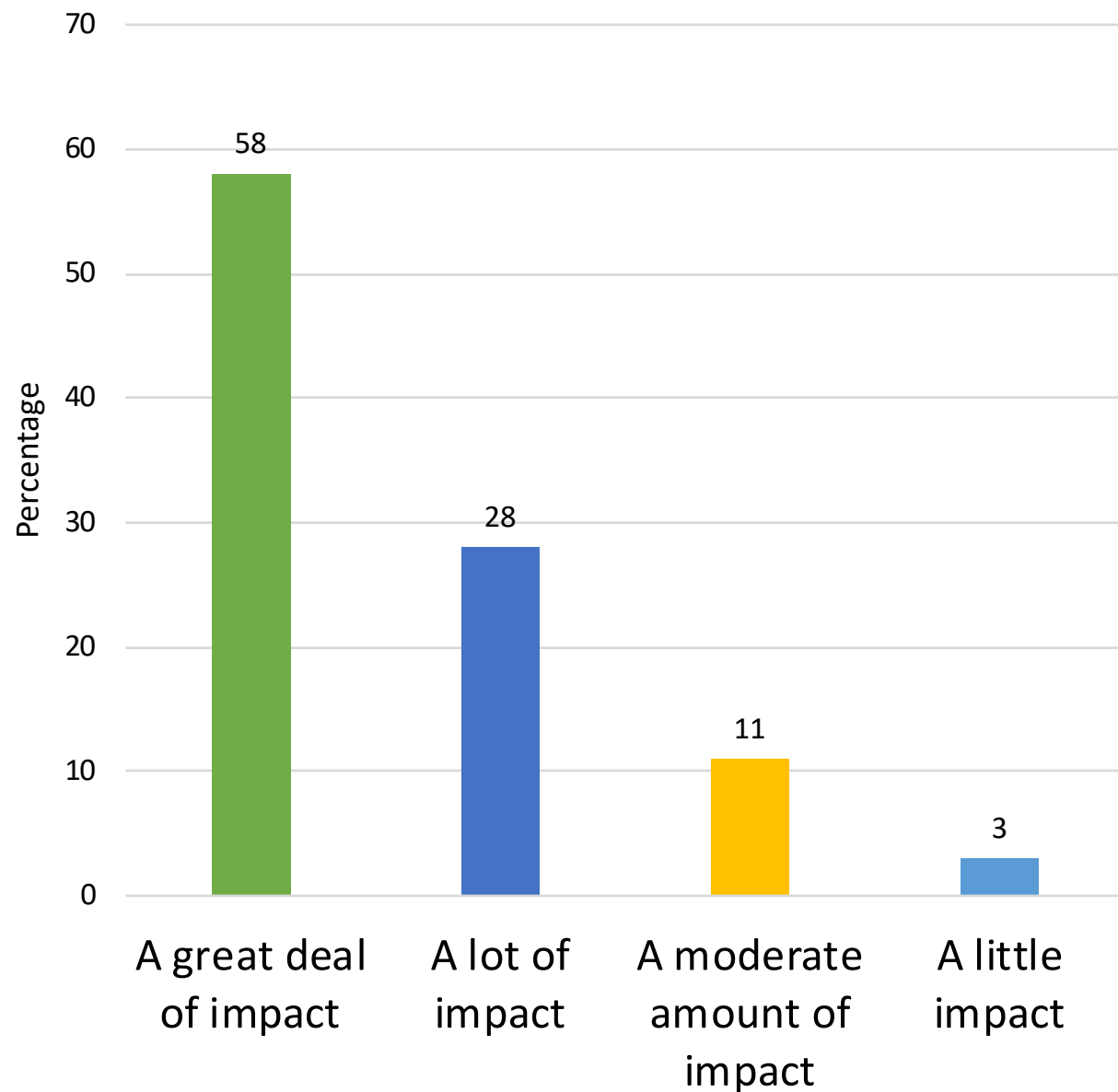
- Burden on their own and families' lives and activities

- Not managed alone by diet, lifestyle change or exercise

- *“Living with IBS with constipation is like 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.”*

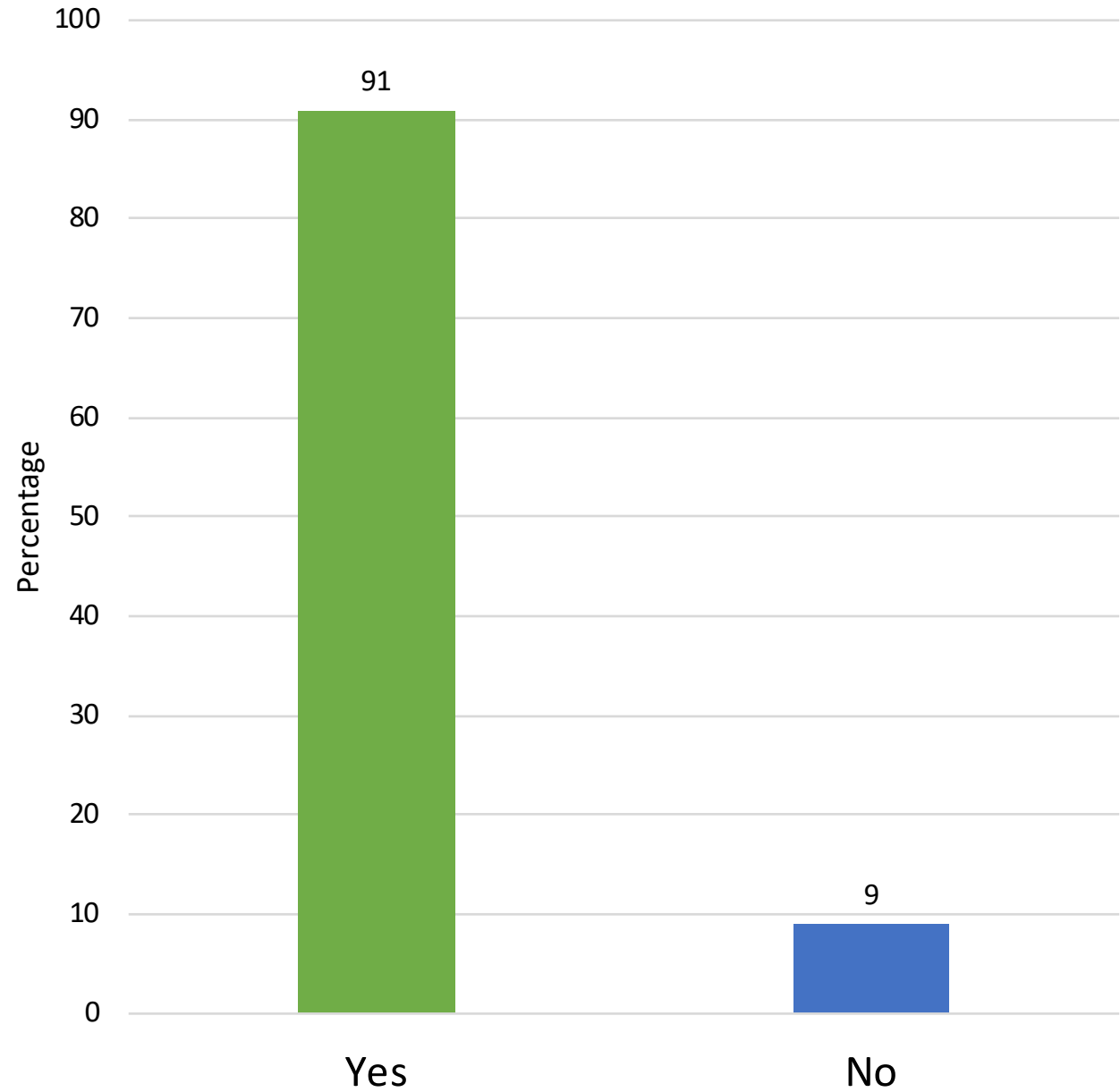
- *“Living in my own world as no one really understands the pains we go through. Housebound, loss of friends, activities, loneliness, and depression.”*

How much of an impact do you feel your IBS has on your quality of life (QOL)?



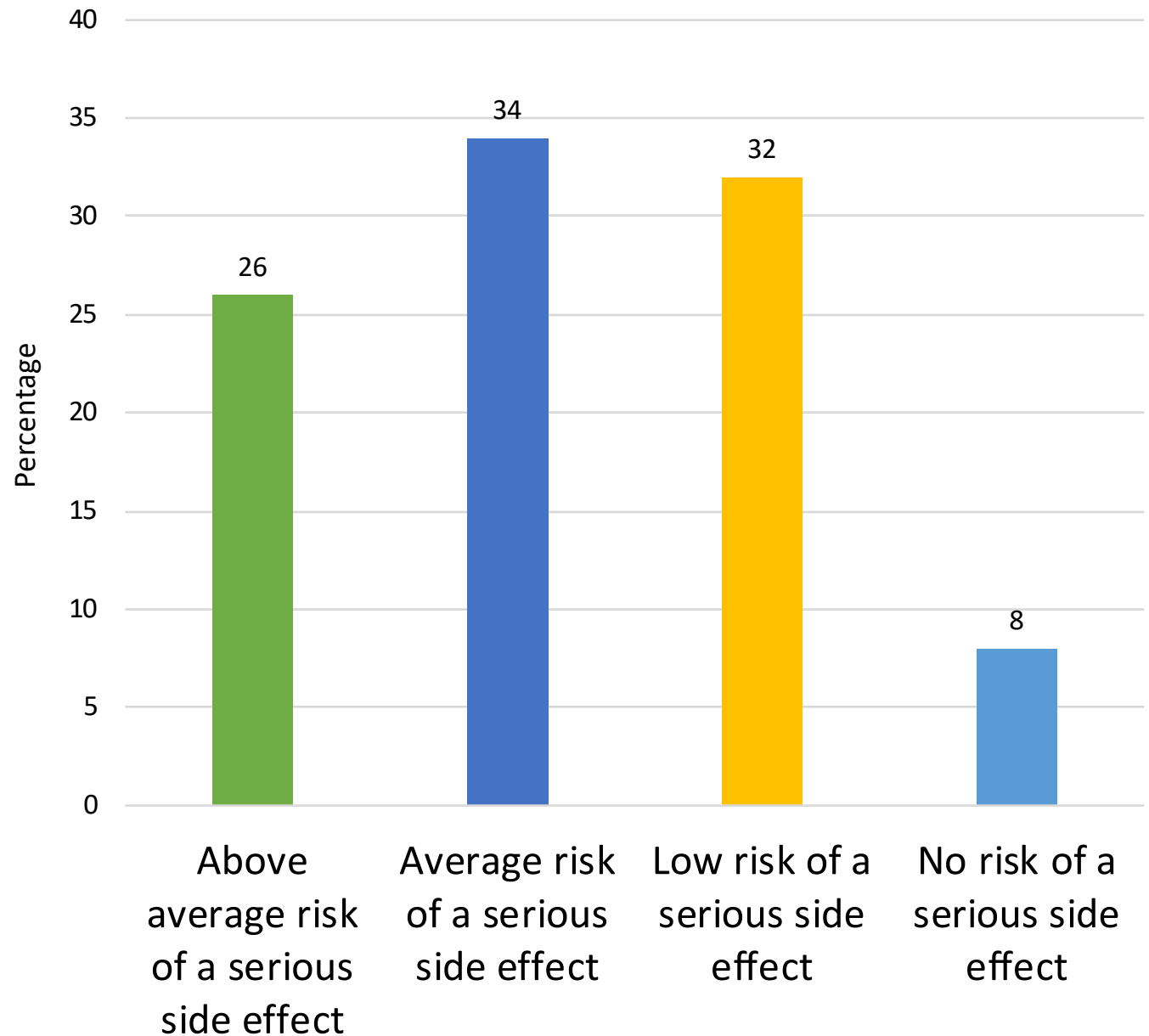
Survey conducted on SurveyMonkey via Facebook and Twitter by IBS Patient Group  
September 2018 by self identified IBS sufferers

Have you ever used a medication to treat your IBS?



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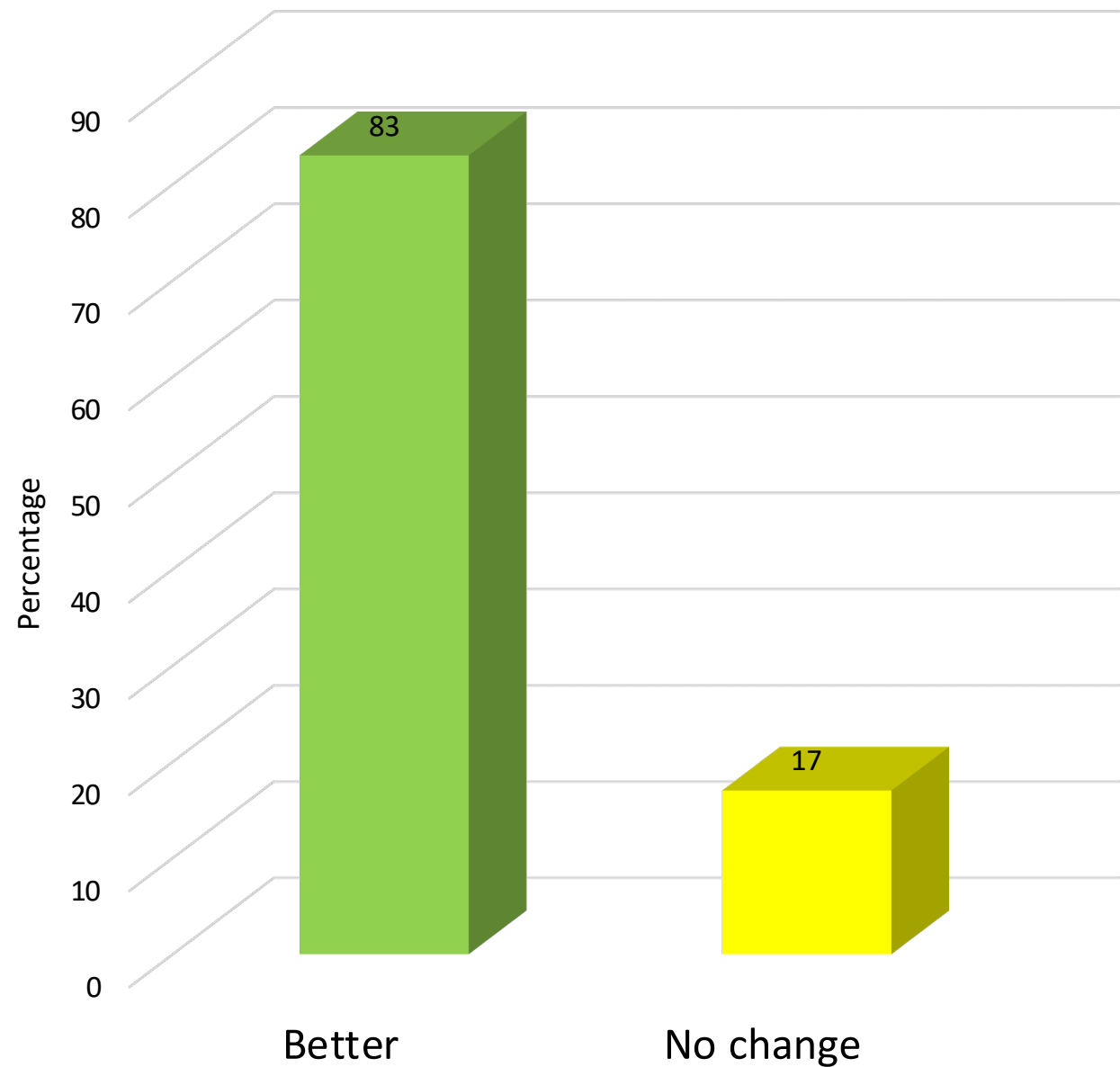
What level of risk of a serious side effect would you be willing to accept to use a medication to relieve a great deal of your IBS symptoms?




Survey conducted on SurveyMonkey via Facebook and Twitter by IBS Patient Group September 2018 by self identified IBS sufferers

# Patients' Perspective:

## QOL while taking ZELNORM



 Survey conducted by IBSgroup.org June 2004– July 2004 with current Zelnorm users

# Conclusion

- Patients' QOL dramatically improved with access to Zelnorm
- Patients are prepared to accept risks
- Patients do not want access restrictions
- Benefits of Zelnorm outweigh the potential risk for adverse side effects if prescribed properly