AN ONLINE STUDY

Gastroparesis Patients: Disease Impact and Medication Risk Assessment

Conducted by the
International Foundation for
Gastrointestinal Disorders

Dear Reader,

Focused and prolonged research into gastroparesis is absolutely crucial to enhance understanding and develop treatment options for those living with this debilitating disease. The International Foundation for Gastrointestinal Disorders (IFFGD) has consistently been at the forefront of encouraging and funding investigators in GI illness. Beginning in 1993, IFFGD has conducted research surveys to gain understanding and determine the needs of those affected by multiple GI disorders. Beginning with a survey to delve into the patient perspective of illness burden for fecal incontinence and continuing with IBS and gastroparesis surveys, IFFGD is continually engaging the community to learn more about the illness experience. We promote collaboration and exchange of research among researchers and clinicians through our research awards. Through IFFGD's efforts to support research, advocacy, educational websites, patient education and publications, we provide support to GI illness patients and their families around the world.

In late 2019, IFFGD conducted a short survey of gastroparesis patients to study quality of life, disease severity, and patient risk assessment when considering medications and clinical trials. This survey was distributed by IFFGD to gastroparesis patients through email and social media. This survey is named the “Gastroparesis Disease Impact and Medication Risk Assessment.” During the 5 weeks the survey was open for data collection, 200 responses were received, offering valuable insight into the needs and desires of gastroparesis patients.

This survey, which contained 18 questions and 3 sections, inquired about the effect of 1) gastroparesis on quality of life, 2) risk versus benefit to achieve improved quality, and 3) opinion on medications deemed high risk. Eighty-four percent of the participants who started this survey completed it in its entirety, highlights of their responses are included. This document includes valuable insight into the needs, desires, and opinions of the gastroparesis community. It is important that as we expand our knowledge of gastroparesis with scientific and medical research, patients are a key participant from start to finish.

Behind every response in this study is a person struggling to understand and manage gastroparesis daily. While most are connected to healthcare providers and receiving some type of treatment, their symptoms continue to be troublesome and their lives are seriously impacted by their disorder. The people who participated in this survey provided honest information on what relief they need and what risks they are willing to assume to achieve that relief. We thank the survey participants for their help as we seek a better understanding of community needs.

Sincerely,

Ceciel Rooker
President
International Foundation for Gastrointestinal Disorders

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Defining Gastroparesis

Gastroparesis (GP) is a disorder characterized by delayed stomach emptying with no evident obstruction or blockage. The movement of food through the stomach and small intestine may slow down or stop completely. Individuals living with gastroparesis may express any combination of the following symptoms;

- **Abdominal pain** – pain varying from dull to sharp that occurs inside the stomach or intestines.
- **Nausea** – a feeling of sickness with an urge to vomit.
- **Vomiting** – bringing food back up from the stomach.
- **Early satiety** – the feeling of being full early, an inability to eat a full meal.
- **Reflux** – a burning sensation in the esophagus.
- **Unexpected weight loss** – the loss of weight without trying.

Gastroparesis is classified under three diagnosis;

- **Idiopathic** – unknown cause.
- **Diabetic** – from nerve damage related to diabetes.
- **Post-surgical** – resulting from injury or scarring after surgery.

Key Findings

Over half of responders are willing to take 11 or more years off their life expectancy to ensure perfect health.

Impact on health:

When asked about their current state of health, on a scale of 0 being the worst possible health (or as bad as death) to 100 being a normal healthy life,

75% of responders said their current state of health was 50 or below.

Impact of drug removal:

When gastroparesis-targeted drugs are taken off the market by the FDA, **48%** of patients are completely dissatisfied.

91% prefer that drugs remain on the market with warnings and precautions in place to allow patients and providers to make educated, safe decisions.

Assuming risks:

Respondents were asked how much risk they would take for a medication that provides total relief from gastroparesis symptoms.

27% of responders are willing to risk a 1 in 100 chance or greater of serious and disabling side effects up to and including a chance of death.

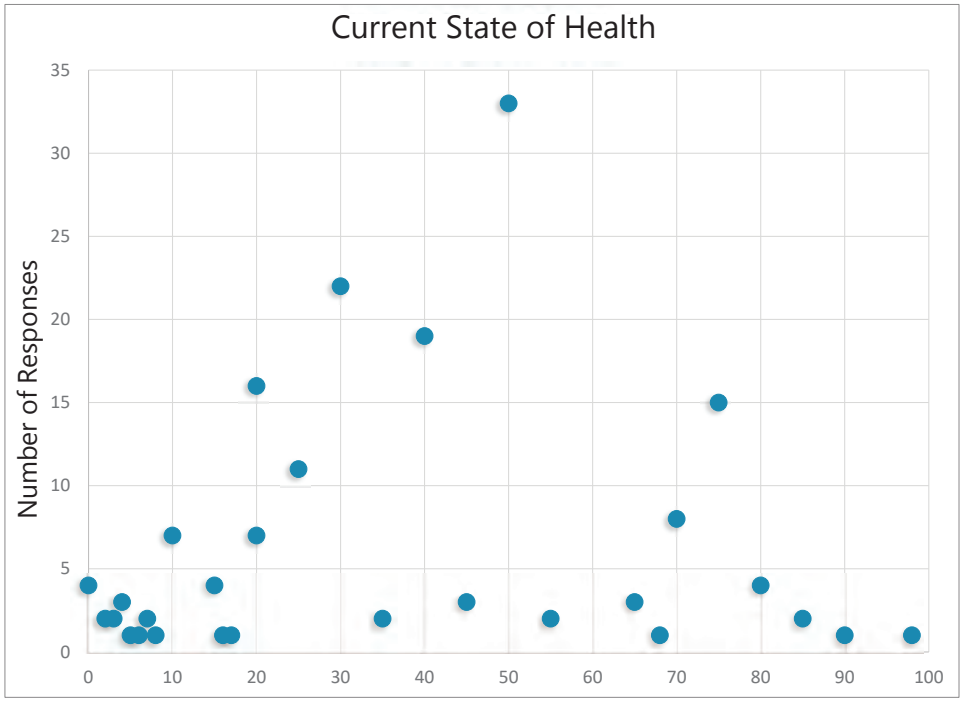
IMPACT OF GASTROPARESIS ON HEALTH

Gastroparesis has a significant impact on a patient's daily living experience and overall health.

Responders rated the impact of gastroparesis on their perceived current state of health. The scale used to rate this question began with 0 being the worst possible health (or as bad as death) to 100 being a normal healthy life.

- The average response was 42.

75% of responders rated their health at 50 or below.



Participants were asked to consider the following scenario:

"Assume that you will continue to live with gastroparesis until age 100, but consider that a perfect state of health can begin immediately and continue for the rest of your life by taking a new medication. This new medication will shorten life by a certain number of years."

Responders then provided the number of years they were willing to take off their lives to obtain a perfect state of health, free of gastroparesis symptoms.

- 34% of responders would be willing to take ***11 to 20 years*** off their life expectancy to ensure perfect health.
- 15% are willing to take ***21 to 30 years*** off their life expectancy to ensure perfect health.

Over half of responders would be willing to take 11 or more years off their life expectancy to ensure perfect health.

EVALUATING RISK ASSOCIATED WITH MEDICATIONS

Responders were asked how much risk they would assume to take a medication that allows them to live with total relief from gastroparesis symptoms. The considerations include risk of death, adverse events, or mild side effects.

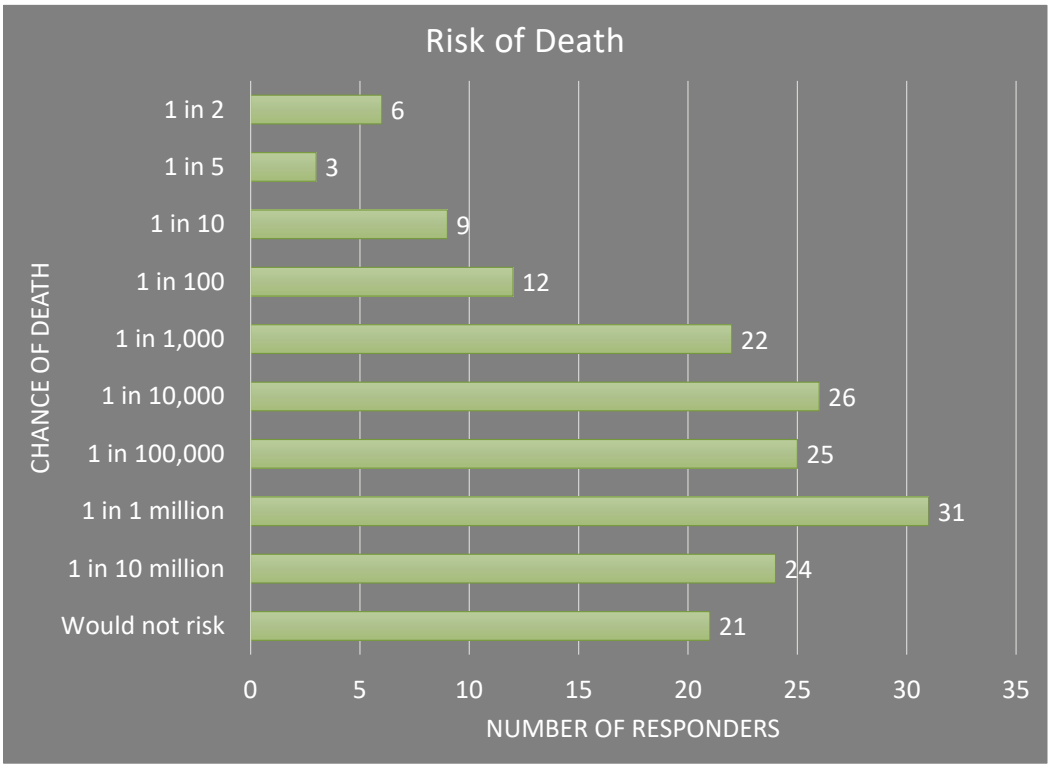
The answer choices included a 1 in 10 million **chance of death** (highly unlikely) with varying degrees to a 1 in 2 chance of death (50% chance) and included "would not take the chance of death."

- 6 individuals stated that they would risk a ***50% chance of death*** to experience gastroparesis symptom relief.

10% of responders are willing to chance a risk of death that is 10% or greater.

Risk of Death

As this graph shows, only 21 out of the 168 survey participants who responded to this question are unwilling to take some degree of risk of death.

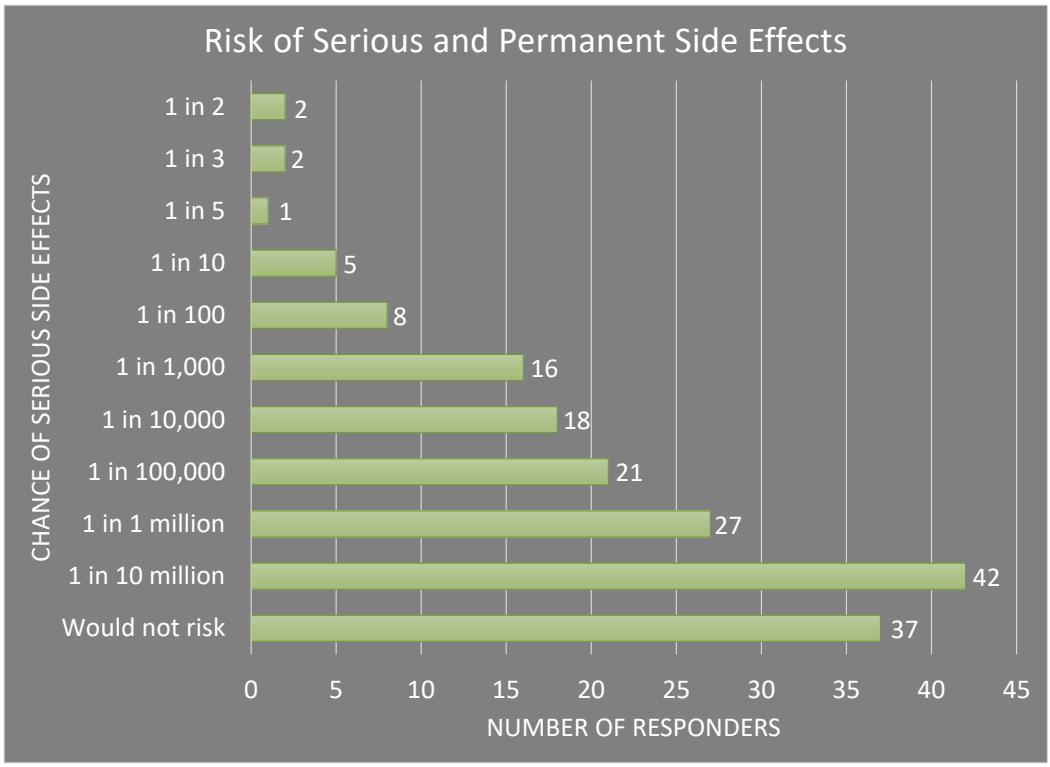


Risk of Serious Adverse Events

Possible **serious adverse events** were assumed as: severe headache, fainting spells, joint pains, or heart irregularities, that impaired your ability to carry on your usual activities.

- 2 individuals will consider a 50% chance.
- Less than 6% are willing to consider a 10% or greater risk of these side effects.
- 21% would take no risk.
- 24% would take a 1 in 10 million chance.

Over 80% of responders are willing to take minimal to no risk of serious adverse effects.

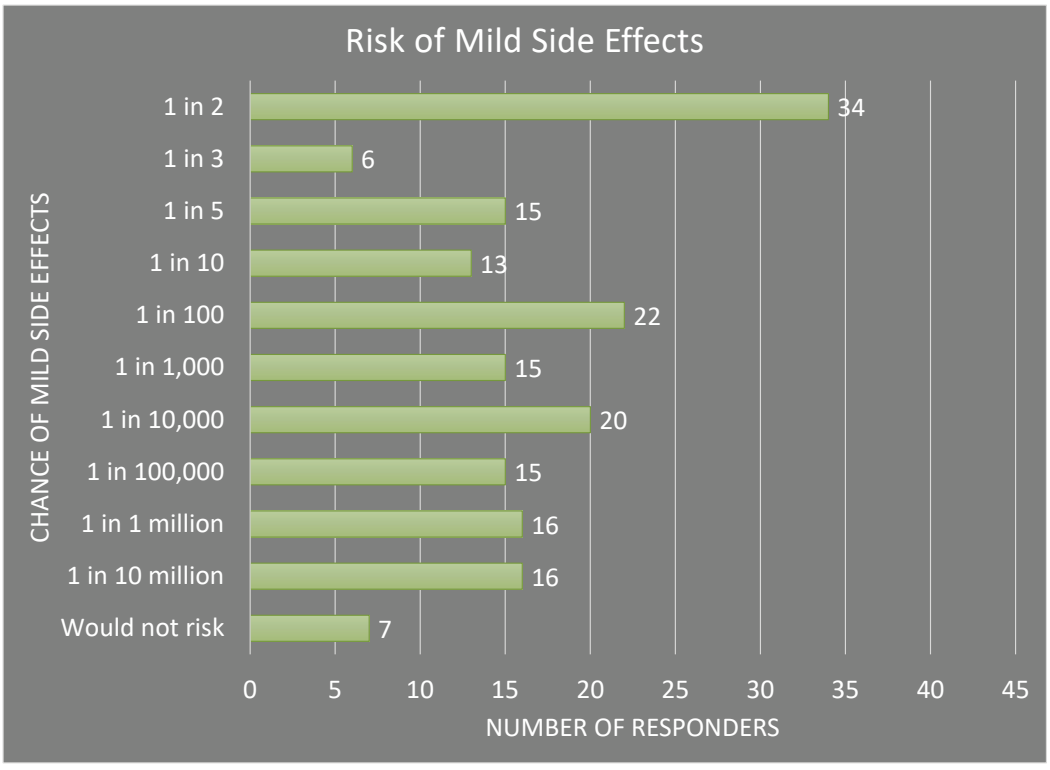


Risk of Mild Side Effects

Possible **mild side effects** may include nausea, fatigue, or dizziness, which would not interfere with your ability to carry on your usual activities.

- Less than 4% would not risk mild side effects.
- More than 38% of responders will risk a 10% or greater chance of mild side effects.

Over 50% of patients surveyed are willing to take a 1 in 100 risk or greater of mild side effects.



REGULATORY INFLUENCE

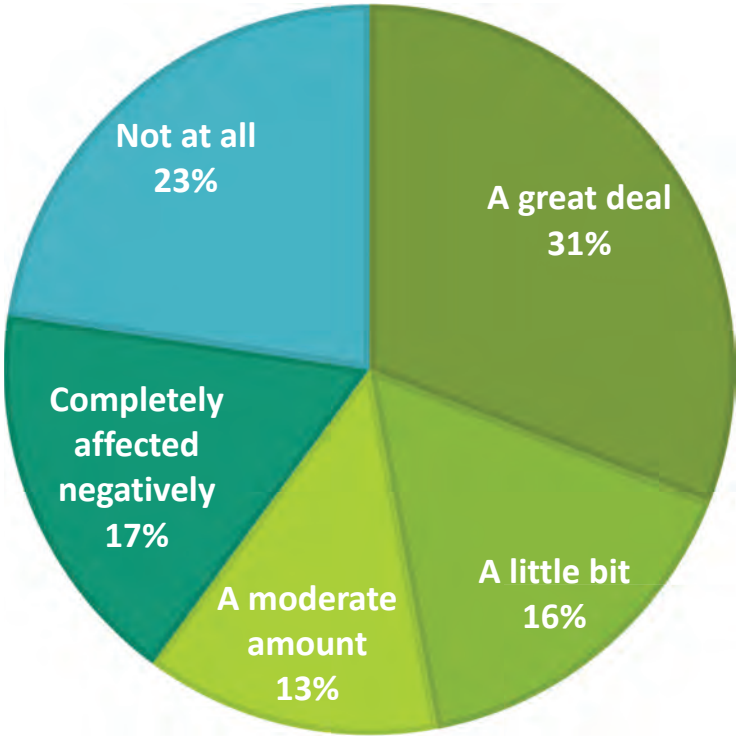
Patients provided their opinion on decisions made by the United States Food and Drug Administration (FDA) regarding medications with possible negative side effects and adverse events. Responders were asked to assume the following situation:

"You were taking a medication for over a year with positive symptom relief. The FDA then decides that the medication may be harmful to others, for example, may cause heart disease. There is some controversy as to whether this is truly the case and the FDA removed the drug from the market until the question of harm is resolved."

Patients would be impacted by this decision, even if they have not had any side effects.

- 31% would be impacted a great deal.
- 23% do not feel this decision would impact them.

Impact of Drug Removal in Patients Without Side Effects



77% would be impacted by this decision in some way.

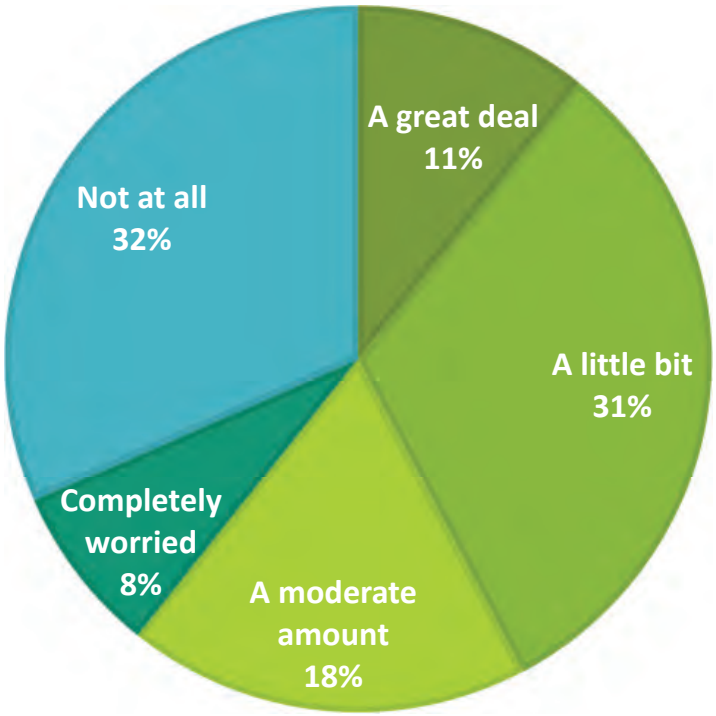
17% feel that they would be completely negatively impacted.

Continuing Medication After Market Removal

Although the intent of drug removal is for the health and safety of those who may take the medication, patients are clearly concerned about the **negative impact** this can have on their **symptom management and relief.**

Responders reflected their concern for continuing the remaining medication supply, considering they have shown no side effects up to that point.

- Over half of responders (63%) would have little to no concern in continuing this medication.
- 8% would be completely worried to continue the medication.

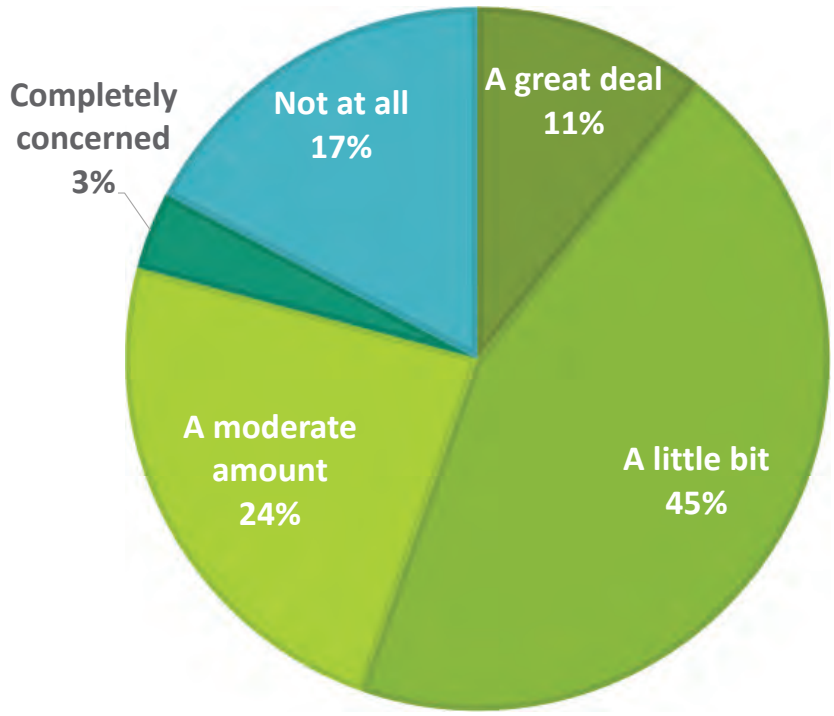


Concern that Removed Medication has Caused Harm

While keeping in mind the current state of health, symptom relief with medication, and lack of negative side effects, participants were asked if they would believe the medication has already done harm to their body.

- 3% would be completely concerned.

62% would have little to no concern that harm has been done.



Satisfaction of Drug Removal

In efforts to protect the public from a potentially harmful medication, we asked participants to assume the FDA removes this medication until safety can be established. The degree of responders' satisfaction of this decision is provided in the table below:

Satisfaction	**Percent**	**Responses**
Not at all satisfied	47.6%	80
A little bit	22.6%	38
A moderate amount	15.5%	26
A great deal	7.7%	13
Completely satisfied	6.5%	11

51% would prefer the medication be placed back on the market.

13% prefer the medication remain off the market.

Investigational Drug Precautions

Respondents were asked to consider the following restrictions to allowing an investigational drug remain on the market. Each line is inclusive of all precautions listed above.

1. There would be a warning label but with no other restrictions (black box warning*).
2. The doctor and patient would sign a form acknowledging possible risk with no other restrictions.
3. Medication could only be prescribed by a GI specialist.
4. A new prescription would be necessary each month.
5. GI specialist will apply for use, patient will sign indicating knowledge of possible side effects with each prescription.

38% feel that this medication should only be prescribed by a GI specialist, with possible continued restrictions in place.

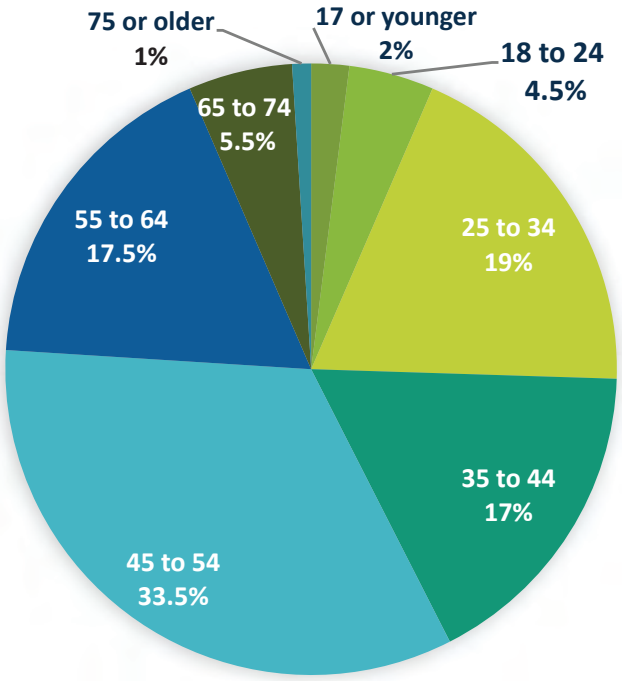
- 29% feel that a black box warning would suffice, with 24% considering this warning in addition to the doctor and patient signing acknowledgment of possible negative side effects sufficient.
- 9% would no longer take the medication based off the precautions and warnings associated with it.

*A **black box warning** is a strict labeling requirement established by the FDA for medications that have known potential for serious and/or life threatening adverse events.

Participant Profile

Patients ranging from 25 to 64 years of age were strongly represented.

33% of responders were 45 to 54 years of age.



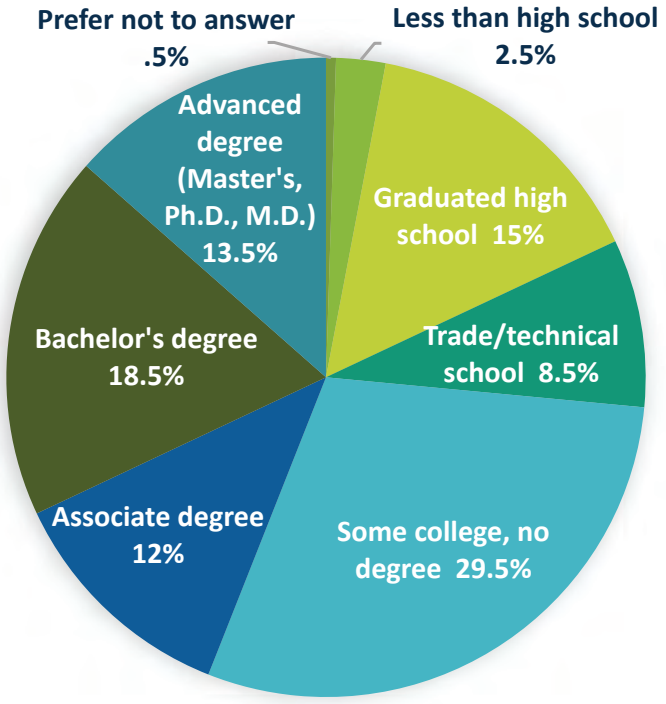
Respondent's marital status:

- 55% Married or living with a domestic partner
- 27% Single or never married.
- 13% Divorced
- 3.5% Separated
- 2.5% Widowed

Income results showed:

- 27% less than $24,999
- 23% at $25,000 to $49,999
- 14% at $50,000 to $74,999
- 8% at $75,000 to $99,999
- 11% over $100,000
- 17% chose not to disclose

According to 2020 United States Census Data, the median American household income is $64,324.



Most participants furthered their education, with 82% of responders having continued education beyond high school.

Our Mission

IFFGD is a nonprofit education and research organization. Our mission is to inform, assist and support people affected by gastrointestinal disorders. IFFGD has been working since 1991 with patients, families, physicians, practitioners, investigators, employers, regulators and others to broaden understanding about gastrointestinal disorders and support research.

International Foundation for
Gastrointestinal Disorders
IFFGD
3015 Dunes West Blvd
Suite 512
Mount Pleasant, SC 29466
Phone: 414.964.1799
E-mail: iffgd@iffgd.org

Learn more at:
iffgd.org
aboutgastroparesis.org
aboutibs.org
aboutincontinence.org
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