H.R.2435, Gluten in Medicine Disclosure Act of 2021

Providing Consistency and Transparency for Consumers
Rep. Tim Ryan (D-OH) & Rep. Steve Stivers (R-OH)

Background

- Celiac disease is a serious, genetic autoimmune disorder in which ingesting gluten causes damage to the villi of the small intestine. The only treatment is the total elimination of gluten-containing products, including wheat, barley, and rye sources.
- According to the Mayo Clinic, the rate of celiac disease has almost quadrupled over the past 50 years.
- The only treatment is the total elimination of gluten-containing products, including wheat, barley, and rye sources. For some, failure to avoid these can lead to life-threatening complications. Currently, this is nearly impossible to determine the presence of gluten in prescription medicine.
- In 2004, the Food Allergen Labeling Consumer Protection Act required packaged food labels to identify all ingredients containing wheat and other allergens. This requirement does not extend to prescription drugs.
- In 2017, the FDA released draft guidance encouraging drug manufacturers to disclose the presence of gluten. But while some manufacturers have taken this step, it has not been implemented consistently.

Gluten in Medicine Disclosure Act (H.R.2435)

- This legislation would require drug manufacturers to label medications intended for human use with the list of ingredients, their source, and whether gluten is present.
- A gluten-containing drug that does not meet these requirements would be considered misbranded under Section 502 of the Federal Food, Drug, and Cosmetic Act.
- This labeling will allow concerned consumers to know, for example, if the starch in their prescription drugs comes from wheat or corn.
- For the nearly 3 million Americans living with celiac disease, that small distinction is an important one.

Support Organizations

- Celiac Disease Foundation

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How to Cosponsor?

- Email Rachel Jenkins (rachel.jenkins@mail.house.gov) in Congressman Ryan's Office or Nick Bush (nick.bush@mail.house.gov) in Congressman Stivers' Office.