

S.3021 The Gluten in Medicine Disclosure Act of 2019:
Providing Transparency for Consumers

Urging You to Support S.3021

Dear Senator _____:

Celiac disease is a serious, genetic autoimmune disorder affecting 3 million Americans. The only treatment is the total elimination of gluten-containing products, including all wheat, barley, and rye sources. For some, failure to avoid these **can lead to life-threatening complications**, including infertility, failure to thrive in children, and even some cancers. Importantly, a Mayo Clinic study revealed that the rate of celiac disease has almost quadrupled over the past 50 years.

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 making it nearly impossible to determine the presence of gluten in prescription medicine.**

After repeated efforts to shed light on this issue, the FDA initiated a draft guidance in 2017 (which is still being finalized), encouraging drug manufacturers to disclose the presence of gluten. While some manufacturers have taken this step, many have not. This leads to anxiety of not knowing whether or not medication is doing more harm than good.

On December 11, 2019, Senator Richard Blumenthal introduced the **Gluten in Medicine Disclosure Act of 2019**, which will require drug manufacturers to label medications intended for human use with a 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 medicine comes from wheat or corn, an important distinction.

Please join Senator Richard Blumenthal in cosponsoring this important piece of legislation to make it easier and safer for individuals with celiac disease or gluten sensitivity to make informed decisions of needed medications. For more information or to cosponsor, please contact Alison Council (Alison_Council@blumenthal.senate.gov) in the office of Senator Blumenthal.

Thank you!

Sincerely,