United States Senate
WASHINGTON, DC 20510

January 7, 2025

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Patrizia Cavazzoni, MD
Director
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Peter W. Marks, MD
Director
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf, Dr. Cavazzoni, and Dr. Marks:

We write to urge you to fully enforce the Federal Drug Administration's Pregnancy and Lactation Labeling Rule. This decade-old rule from your agency addressed significant problems with the safety information that medication labels provided to pregnant women and nursing mothers. However, 17 medications currently on the market still do not comply with the rule and their safety labels fail to provide women with clear safety information. These non-compliant medications include commonly used products such as antibiotic drugs, multiple types of eyedrops, and a yeast infection treatment. We urge you to immediately take steps to ensure that all marketed medications comply with the Pregnancy and Lactation Labeling Rule.

Prior to the Pregnancy and Lactation Labeling Rule, the pregnancy and lactation labeling system for drugs consisted of five letter risk categories – A, B, C, D, and X. These risk categories gave an over-simplified view of the product risk, and did not provide enough clinically relevant information about potential risks. In particular, for drugs without satisfactory studies in pregnant women, category C conflated a range of animal evidence bases, all under the label "cannot rule out risk". Drugs where animal studies had indicated a risk to a fetus, and drugs with no animal studies at all, were all labeled category C. This meant that women and their doctors had no clinical guidance about whether a category C drug had demonstrated a risk in an animal study. I am grateful that the FDA listened to feedback from physicians and other stakeholders, and published the Pregnancy and Lactation Labeling Rule in 2015.

The Pregnancy and Lactation Labeling Rule removed the pregnancy letter risk category, replacing it with a straightforward summary of available risk information related to pregnancy and lactation. Drug packaging inserts must now contain individualized narrative summaries for

each medication that includes the risks of using a drug during pregnancy and lactation, a discussion of the data supporting that summary, and relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. This rule applies to all drugs approved by the FDA after June 30, 2015, and requires that all labels be continually updated as new information becomes available.

However, despite nearly a decade of implementation, according to information provided to our offices by the FDA, approximately 17 drugs on the market do not comply with current safety labeling rules for pregnancy. This includes commonly used products such as antibiotic drugs, yeast infection treatments, and multiple types of eyedrops. When a pregnant woman is prescribed one of these non-compliant drugs, she may not be able to determine if a drug is safe to take while pregnant or nursing. Similarly, her health care provider may not be able to counsel her on the health risks when taking this drug, because the risks are presented in a way that is hard to interpret. This situation could threaten the health of a woman during pregnancy or her and her baby's health during breastfeeding.

We urge the FDA to do everything in its power to quickly bring these 17 drugs into compliance with the labeling rule. We request that the FDA publish a list of noncompliant products so that that physicians, pharmacists, and patients are aware of the labeling issues.

Thank you for your attention to this urgent matter.

Sincerely,

Margaret Wood Hassan
United States Senator

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United States Senator