

# Prescription Drugs

## Current language

“For prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent shall be deemed to be a clear and reasonable warning.”



## Proposed Language and Existing Examples

“... [T]he labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent must include information concerning cancer or birth defects or other reproductive harm...”

### Cancer (From Existing Warning)

Women who currently have or have had breast cancer should not use Beyaz because breast cancer is a hormonally-sensitive tumor.

### Birth Defects/ Reproductive Harm (From Existing Warning)

Birth defects and decreased IQ following *in utero* exposure; only use to treat pregnant women with epilepsy or bipolar disorder if other medications are unacceptable; should not be administered to a woman of childbearing potential unless essential (5.2, 5.3, 5.4)