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)