The Food and Drug Administration’s Pregnancy and Lactation Labeling Rule (2014) [1]

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In 2014, the United States Food and Drug Administration [7] published the Pregnancy and Lactation Labeling Rule to amend previous guidelines for the prescription of drugs for pregnant and lactating women. The 2014 Pregnancy and Lactation Labeling Rule was intended to increase the safety and efficacy of prescription drugs by making drug labels easier for physicians to understand and utilize. The Pregnancy and Lactation Labeling Rule restructured drug labels and required that they include narratives describing drug-associated risks to women and fetuses, rather than using complicated letter categories. The Pregnancy and Lactation Labeling Rule changed the framework for drug labeling, making it easier for doctors to prescribe safe and effective drugs to pregnant women, lactating women, and people of reproductive capacity.

In the US, the FDA ensures the safety and efficacy of drugs by regulating drug manufacturers. In the first step of this process, the FDA proposes a possible rule and makes the draft rule available for public comment. Next, the FDA reviews and incorporates those comments. Finally, they publish the revised rule, which has the force and effect of law. Drug manufacturers and other entities within the FDA’s jurisdiction must follow the rule set by the FDA. One kind of rule the FDA can set involves drug labeling. Drug labels contain information that is meant to guide how physicians and pharmacists prescribe drugs and how patients use drugs. The Pregnancy and Lactation Labeling Rule regulates the labels on drug containers, the handouts that come with prescription drugs, as well as the information that physicians use to prescribe those drugs.

For much of the twentieth century, drug labels did not include any information about the effects drugs might cause on pregnant women and their fetuses. The FDA began regulating drugs specifically used during pregnancy [8] in 1979 following several incidents where drugs caused negative effects in pregnant women and their fetuses. One incident involved thalidomide, a drug developed in the Germany in the 1950s that doctors prescribed as a sedative and to reduce nausea in pregnant women. Thalidomide was advertised as safe for pregnant women. However, the drug caused limb deformities in children born to mothers who took the drug during pregnancy [8]. Another incident involved diethylstilbestrol, or DES, a drug marketed to pregnant women in the 1970s to prevent early labor. Researchers later found that DES caused cancer, and many female children born to mothers who took DES had a higher risk of developing a vaginal tumor called a clear carcinoma. That drug was discontinued in 1971. The FDA passed their first rule regulating the format and content of prescription drug labels in 1979. The 1979 rule established a five-category system in which letters were used indicate increasing risk a drug posed to the pregnant woman or fetus [8], with A indicating low risk and X indicating high risk. According to historians, the 1979 rule had several problems. First, the information pertaining to pregnant women was difficult to find. Second, the label did not include sufficient information to guide doctors’ prescription of drugs.

The 1979 rule was amended in 2006 when the FDA issued the Physician Labeling Rule. Starting in 2006, the FDA eliminated the pregnancy [8] information in the “Precautions” section on labels and moved it to three new specific populations sections titled “Pregnancy,” “Labor and Delivery,” and “Nursing Mothers.” The 2006 Physician Labeling Rule continued to use the letter categories to indicate the drug-associated risks posed to mother and fetus [8]. The new rule made that information easier to find.

The pregnancy [8] categories established in 1979 and maintained in 2006 were criticized by several groups. According to the Pediatric Advisory Committee within the FDA, the labels established by the 1979 Rule and maintained in the Physician Labeling Rule were overly simplistic and could lead to physicians or patients misinterpreting information. The Teratology Society, a scientific society focused on birth defects [10], did not support the use of standardized categories and asserted that the categories would not give people an accurate understanding of the risks associated with certain drugs. The American College of Obstetricians [11] and Gynecologists, or ACOG, indicated that the pregnancy [8] categories were confusing and unhelpful for patients and physicians. ACOG also requested that the FDA replace pregnancy [8] categories with written sections.

In 2014, the FDA issued the Pregnancy and Lactation Labeling Rule, which discontinued the letter categories in the “Pregnancy” section and replaced them with narrative descriptions of risk. The FDA first drafted the Pregnancy and Lactation Labeling Rule in 2008 and published it in 2014. The 2014 Pregnancy and Lactation Labeling Rule restructured the content of the 2006 Rule and introduced three headings, “Pregnancy,” “Lactation,” and “Females and Males of Reproductive Capacity.” Within each of those headings, the Pregnancy and Lactation Labeling Rule specifically outlines what manufacturers must include on drug labels. The “Pregnancy” section includes the requirements for labels of drugs that women might use during pregnancy [8]. The “Lactation” section includes the requirements for labels of drugs that women might use while breastfeeding. The “Females and Males of Reproductive Capacity” section includes the requirements for labels of drugs that might impact fertility.
Sources


2. Feibus, Karen “FDA’s Proposed Rule for Pregnancy and Lactation Labeling: Improving Maternal Child Health through Well-
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