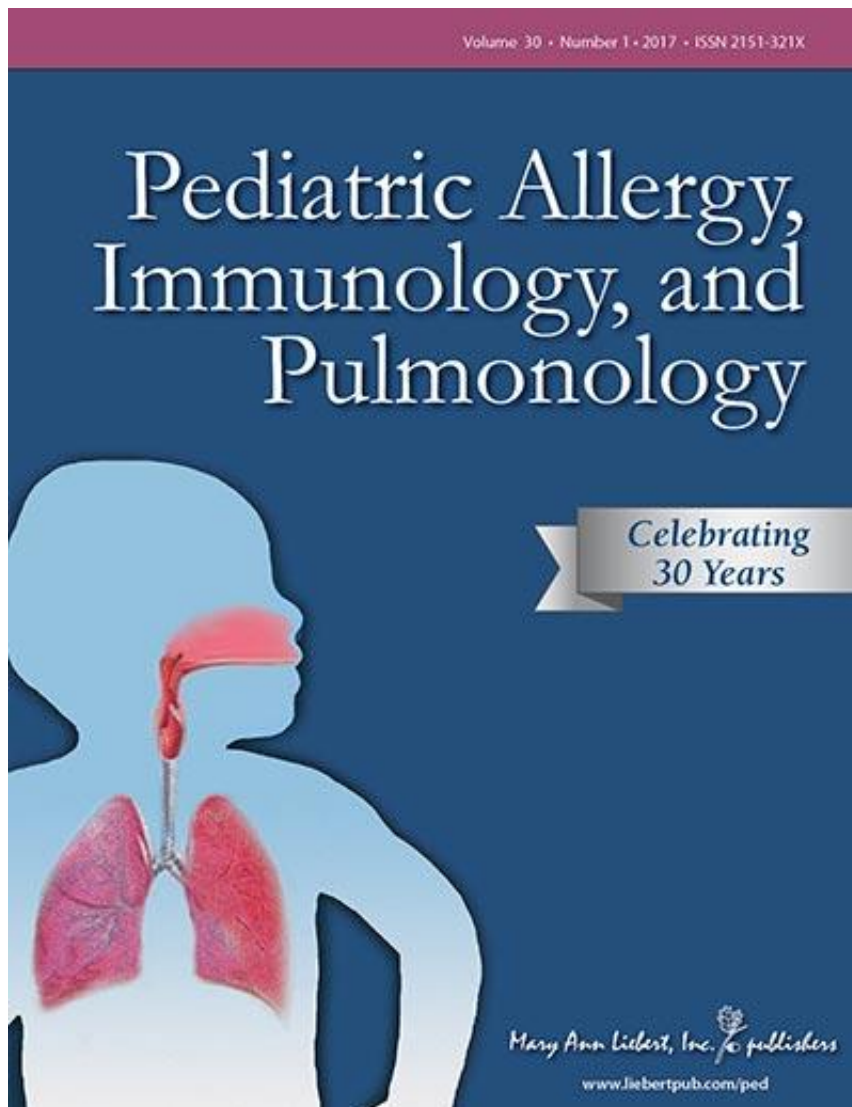


FDA rule improves labeling of medications used during pregnancy and lactation

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Credit: Mary Ann Liebert, Inc., publishers

The new U.S. Food and Drug Administration's (FDA's) Pregnancy and Lactation Labeling Rule should help healthcare providers better explain to pregnant and breastfeeding patients the benefits and risks of taking a specific medication. The new labeling format provides a summary of the evidence-based risks, replacing the previous that were too often misinterpreted, according to an article published in *Pediatric Allergy, Immunology, and Pulmonology*, a peer-reviewed journal from Mary Ann Liebert, Inc., publishers. The article is available free on the *Pediatric Allergy, Immunology, and Pulmonology* website.

Miriam Dinatale, DO, Leyla Sahin, MD, Tamara Johnson, MD, Tammie Brent Howard, RN, and Lynne Yao, MD, Food and Drug Administration, Silver Spring, MD, present a clear description of the new FDA labeling rule, how it is being implemented, and how it improves on the existing labeling system in the article entitled "Medication Use During Pregnancy and Lactation: Introducing the Pregnancy and Lactation Labeling Rule." More than half of pregnant women report taking at least one medication. These new labeling requirements detail the risks of a prescription drug or biological product for the mother, fetus, breastfeeding infant, and women and men of reproductive potential.

"According to a recent study by the Centers for Disease Control and Prevention (CDC) on Family Growth in the U.S., approximately 50% of women between ages 15 and 44 responded that they intend to have a child in the future. Healthcare providers responsible for counseling patients who are pregnant, planning to become pregnant, and those who are breastfeeding need a reliable source of information about prescription medications," says *Pediatric Allergy, Immunology, and Pulmonology* Editor-in-Chief Mary Cataletto, MD, Professor of Clinical Pediatrics, Stony Brook University School of Medicine. "The new labeling requirement provides a more user-friendly presentation of studies, registries, and available information that can be used to assist

providers in discussing [medication](#) risks and benefits with their patients."

More information: Miriam Dinatale et al, Medication Use During Pregnancy and Lactation: Introducing the Pregnancy and Lactation Labeling Rule, *Pediatric Allergy, Immunology, and Pulmonology* (2017). [DOI: 10.1089/ped.2017.0772](https://doi.org/10.1089/ped.2017.0772)

Provided by Mary Ann Liebert, Inc

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