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### Authors

Beroukhim, Kevin  
Abrouk, Michael  
Farahnik, Benjamin

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**Commentary**

**Impact of the Pregnancy and Lactation Labeling Rule (PLLR) on Practicing Dermatologists**

**Kourosh Beroukhim BS<sup>1</sup>, Michael Abrouk BS<sup>2</sup>, Benjamin Farahnik BA<sup>2</sup>**

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<sup>1</sup>David Geffen School of Medicine at the University of California, Los Angeles, Department of Dermatology, Los Angeles, California

<sup>2</sup>University of California, San Francisco, Department of Dermatology, San Francisco, California

**Correspondence:**

Kourosh Beroukhim  
David Geffen School of Medicine at the University of California, Los Angeles, Department of Dermatology,  
Los Angeles, California  
10833 Le Conte Ave, Los Angeles, CA 90095  
Tel: (310) 272-6025  
Fax: (415) 502-4126  
kberoukhim@mednet.ucla.edu

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**Abstract**

On June 30<sup>th</sup> 2015, the FDA instituted a new system for the categorization of drug safety during pregnancy and lactation, known as the Pregnancy and Lactation Labeling Rule (PLLR), which replaces the “A, B, C, D, X” pregnancy labeling categories. The new rule will apply to all newly approved prescription medications, with a staggered phase-in for prescription drugs approved prior to the effective date. In this article, we provide a brief description of the major changes introduced by the PLLR and discuss the major implication of this new categorization system for clinical dermatologists.

**Keywords: Drug Labeling; Pregnancy and Lactation; Health Policy; Evidence-Based Medicine**

**Commentary**

On June 30<sup>th</sup> 2015, the FDA instituted a new system for the categorization of drug safety during pregnancy and lactation, known as the Pregnancy and Lactation Labeling Rule (PLLR) [1]. The PLLR replaces the “A, B, C, D, X” pregnancy labeling categories for medications, which have been in place since 1979. The following article provides a brief summary of the PLLR and highlights the potential implications of this system for practicing dermatologists.

The most prominent change within the PLLR is the absence of the “A, B, C, D, X” pregnancy lettering categories. In lieu of the relatively simple, yet often ambiguous risk stratification system provided by the traditional lettering system [2], the PLLR requires an individualized narrative summary of the risk profile for each drug. According to the Food and Drug Administration, each narrative will summarize the risks associated with using a medication or allowing the disease to go untreated, list all relevant sources of data or state specifically if there is none, and address any information available from drug registries.

In addition, the PLLR introduces three novel categories for labeling populations. These consist of “Pregnancy, “Lactation,” and “Females and Males of Reproductive Potential.” The “Pregnancy” category will include a required pregnancy exposure registry with a summary of data available on drugs used in pregnancy. The “Lactation” category will include information on the extent to

which the drug is transmitted through breast milk as well as considerations of risk to the infant. Finally, the “Females and Males of Reproductive Potential” category will discuss recommendation for contraception and pregnancy testing while the drug is administered, as well as any risk of infertility associated with the drug.

The changes introduced by the PLLR will certainly have major implications for practicing dermatologists. Most prominently, the PLLR will eliminate the ambiguity associated with the previous lettering system in favor of narratives specific to the data available for each drug. This will be particularly pertinent for medication such as the biologics, for which randomized controlled trials involving pregnant and lactating women are precluded due to ethical concerns. Whereas such drugs were previously categorized into a letter group despite the lack of sufficient data, the PLLR will present any known risks while also addressing the shortage of adequate data available about the use of the drug during pregnancy and lactation. These changes will afford physicians a more in depth understanding of the risks associated with each drug, and allow more individualized clinical decisions based on the needs of a particular patient. On the other hand, the lack of a universal stratification system necessarily makes the decision making process more complex and time consuming for busy practitioners, who will also have to meet the challenge of communicating the data presented in each narrative in lay terms fit for patients [3].

The PLLR applies only to prescription medications, with no effects on over-the-counter drugs. All medications approved following the effective date of June 30, 2015 will be immediately required to meet the labeling requirements set by the PLLR. All other prescription drugs will be phased in by June 30, 2018. For a more detailed overview of the PLLR, please visit <http://federalregister.gov/a/2014-28241>.

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