

Maternal Depression

FDA Activities

Leyla Sahin, MD, FACOG

US FDA

Center for Drug Evaluation and Research, Office of New Drugs

Division of Pediatric and Maternal Health

Overview

- Background
- Drug research/development
- Data collection on the safety of drugs used to treat depression in pregnancy
- Drug labeling in pregnant and lactating women
- Collaborative activities with external stakeholders

Background

- FDA mission is to protect the public health by ensuring the safety and effectiveness of drugs
- Drug development usually excludes pregnant women
- Pregnancy drug safety data is usually collected after drug approval

Maternal Depression Drug Research

- Provide oversight to:
 - Pharmaceutical industry developing treatments in post-partum depression
 - Academic investigators (maternal antidepressant studies)
 - Observational studies
 - Pharmacokinetic studies

Data collection on safety of drugs used to treat maternal depression

- Encouragement of pharmaceutical industry to collect data
- FDA Pregnancy Registry website
 - Lists the National Antidepressant Pregnancy Registry



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Pregnancy Registries

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Many women need to take medicine while they are pregnant. Some women take medicines for health problems, like diabetes or high blood pressure, that can start or get worse when a woman is pregnant. Some women use medicine before they find out they are pregnant.

A pregnancy exposure registry is a study that collects health information from women who take prescription medicines or vaccines when they are pregnant. Information is also collected on the newborn baby. This information is compared with women who have not taken medicine during pregnancy.

Enrolling in a pregnancy exposure registry can help improve safety information for medicines used during pregnancy and can be used to update drug labeling. Learn more about how you can help.

[Pregnant Women](#)
[Health Professionals](#)
[Find a Registry](#)

Pregnancy and Lactation Labeling Rule (PLLR)

- Came into effect on June 30, 2015
- Revised pregnancy and lactation labeling
 - Replaced pregnancy letter categories with clinically relevant summaries of available information
 - Focus on human data
 - Considerations for background risk in the general population and the disease population
 - Inclusion of contact information for Pregnancy Registry, if one exists

Collaborations with Perinatal Psychiatry groups

- April 28, 2017 meeting being planned by Massachusetts General Hospital Perinatal Psychiatry Research Program to discuss drug safety data collection and communication of data in labeling
- Presentations on PLLR at Marce Society for Perinatal Mental Health meetings