

# Complying with the New Pregnancy and Lactation Labeling Rule (PLLR)...



Will You Be Ready?

Reviews by Experts. Reviews Ready for Use.

By the Organization of Teratology Information Specialists (OTIS)



## Our Experts Will Help You Streamline



The PLLR implementation has created an urgent need for current and comprehensive reviews of existing data and summaries of fetal and lactation risks. Thousands of prescription medications fall under the PLLR timeline over the next five years, an overwhelming task for many companies.

## OTIS is here for you.

- We provide expert consultation to pharmaceutical companies to produce the required comprehensive reviews of existing data and summaries of fetal and lactation risks for prescription medications.
- Our experts provide language that clearly conveys the data and will support labeling content.

## Why choose OTIS?

### **We've been doing this a long time.**

The Organization of Teratology Information Specialists (OTIS) is a professional scientific society. OTIS is made up of teratologists, experts on the effects of exposures during pregnancy and lactation. Thorough literature reviews, synthesis and translation of the data are all part of the OTIS communication process. OTIS has been perfecting this process for more than 30 years, connecting world-renowned experts in the field of birth defects research with the general public.

### **We translate data about medications in pregnancy and lactation for health care providers every day.**

OTIS is a 501(c)(3) nonprofit organization and has established a national call routing system. Since 2002, anyone in North America calling the toll-free number, 1-866-626-6847, has been routed to an affiliated service to speak with an expert. This service network was later renamed “MotherToBaby” and has evolved into communicating exposure risks to the public through a variety of innovative ways that include written fact sheets, online articles, by telephone, live web chat and texting.



Our experts **include world-renowned teratologists**; members who already provide comprehensive, evidence-based reviews for groups like TERIS and Reprotox.®

### OTIS, Inc. Board:

**Stephen R. Braddock, MD**, OTIS President

**Melissa S. Tassinari, PhD**, retired Sr. Clinical Advisor, US Food and Drug Administration

**Sarah G. Običan, MD**, University of South Florida Morsani College of Medicine

**Katherine L. Wisner, MD, MS**, Northwestern University Feinberg School of Medicine

**Christina D. Chambers, PhD, MPH**, OTIS President-Elect, Ex-Officio Member

### Advisory Board:

**Philip O. Anderson, Pharm D**, Author of LactMed® database

**Gerald G. Briggs, B Pharm, FCCP**, Co-Author of *Drugs in Pregnancy and Lactation*

**Cheryl S. Broussard, PhD**, Centers for Disease Control and Prevention, NCBDDD

**Alicia B. Forinash, Pharm D, FCCP, BCPS, BCACP**, Co-Author of *Drugs in Pregnancy and Lactation*

**Jan M. Friedman, MD, PhD**, TERIS Principal Investigator

**Janine E. Polifka, PhD**, TERIS Project Director

**Anthony R. Scialli, MD**, Reprotox® Director

## Collaborating with OTIS Will Make the PLLR Update Process Easy for You

### Advisory Board

The Advisory Board was established to develop and initiate the safety literature review program for use in PLLR labeling.



**EXHAUSTIVE  
LITERATURE  
SEARCH**



**CRITICAL  
SUMMARY**



**EXPERT  
REVIEW**



**REPORT**



# Take Advantage of Our Unique Expertise and Experience to Meet Your Deadlines

OTIS has been providing evidence-based, medication risk assessments during pregnancy and lactation for more than 30 years. Capitalizing on this experience will save you time and help streamline Pregnancy and Lactation Labeling Rule compliance.

## Contact info:

Organization of Teratology Information Specialists (OTIS)  
Attn: PLLR  
5034A Thoroughbred Lane  
Brentwood, TN 37027  
615-649-3082

[contactus@otispregnancy.org](mailto:contactus@otispregnancy.org)

For more information, please visit: [www.MotherToBaby.org/OTISInc](http://www.MotherToBaby.org/OTISInc)

OTIS, Inc. is a wholly owned  
Benefit Corporation of the  
Organization of Teratology  
Information Specialists.

