



# Meeting of the Risk Communication Advisory Committee

March 5, 2018

FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, MD 20993

## AGENDA

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The Risk Communication Advisory Committee will discuss communicating risk information about fetal effects in product labeling according to the Pregnancy and Lactation Labeling Rule (PLLR), perception of risk and factors important to patients and prescribers, and societal factors that impact treatment decisions, to effectively assist patients and prescribers to make informed decisions about use of prescription drugs and vaccines in pregnancy.

8:00 a.m. Call to Order and Opening Remarks **Susan J. Blalock, Ph.D., M.P.H.**  
Chair  
Risk Communication Advisory Committee

Conflict of Interest Statement **Lee Zwanziger, Ph.D.**  
Designated Federal Officer  
Risk Communication Advisory Committee  
FDA

8:10 a.m. Opening Remarks **Malcolm J. Bertoni, M.S.**  
FDA

### FDA PRESENTATIONS

8:15 a.m. Welcome / Opening Remarks **Lynne P. Yao, M.D.**  
FDA

8:30 a.m. An Evolution of Labeling Information for Pregnant Women: PLLR History and Background **Catherine Roca, M.D.**  
FDA

8:50 a.m. Fulfilling the Intent of PLLR: Current Approaches and Challenges **Leyla Sahin, M.D.**  
FDA

### GUEST SPEAKER PRESENTATIONS

9:10 a.m. Physicians' Perspective of the New Pregnancy and Lactation Labeling: Survey Results **Jennifer A. Namazy, M.D.**

9:30 a.m. Break



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9:45 a.m.	Communicating Risk in an Environment of Uncertainty	<b>Michael F. Greene, M.D.</b>
10:15 a.m.	Prescribing for Pregnant Psychiatric Patients: Progress Report	<b>Katherine L. Wisner, M.S., M.D.</b>
10:45 a.m.	Communication: Advisory Committee on Immunization Practices (ACIP) Recommendations and Vaccine Uptake by Pregnant Women	<b>Laura E. Riley, M.D.</b>
11:15 a.m.	Communicating Teratogen Information Effectively: The Teratogen Information Service (TIS) Perspective	<b>Elizabeth Conover, M.S., APRN</b>
11:45 a.m.	Lunch	
12:45 p.m.	Open Public Hearing	
1:45 p.m.	A Patient Perspective: Pregnancy and Lactation Labeling Rule - A Modern Day Medical X Factor	<b>Jamie Zahlaway Belsito</b>
2:15 p.m.	Pregnancy and Lactation Labeling: A Law and Ethics Perspective	<b>Kayte Spector-Bagdady, J.D., MBioethics</b>
2:45 p.m.	Pregnancy and Lactation Labeling Rule (PLLR) from an Industry Perspective	<b>Traci J. Lee, Pharm.D.</b>
3:15 p.m.	Break	
3:30 p.m.	Clarifying Questions	
4:00 p.m.	Charge to Committee/Committee Discussion	<b>Jodi Duckhorn</b> FDA
5:00 p.m.	Adjournment	<b>Susan J. Blalock, Ph.D., M.P.H.</b> Chair Risk Communication Advisory Committee