Meeting of the Risk Communication Advisory Committee

Mar 5-6, 2018

SUMMARY MINUTES

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

Topic: The committee discussed the impact of pregnancy and lactation labeling information in prescription drug and biological products as modified under the Pregnancy and Lactation Labeling Rule.

These summary minutes for the March 5-6, 2018, meeting of the Risk Communication Advisory Committee of the Food and Drug Administration were approved on April 23, 2018.

I certify that I attended the March 5-6, 2018, meeting of the Risk Communication Advisory Committee meeting of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/S/

Lee Zwanziger, Ph.D.
Designated Federal Officer, RCAC

/S/

Susan Blalock, Ph.D.
Chairperson, RCAC

U.S. Food and Drug Administration
Office of the Commissioner | Office of Planning | Risk Communication Staff
10903 New Hampshire Avenue, Silver Spring, MD 20993
RCAC@fda.hhs.gov | www.fda.gov

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The following is a final report of the meeting of the Risk Communication Advisory committee held on Mar 5-6, 2018. A verbatim transcript will be available in approximately three weeks and posted to the FDA website at: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/ucm594576.htm

Purpose of Meeting

The Risk Communication Advisory Committee to the Food and Drug Administration (FDA) met on Mar 5-6, 2018, to discuss the impact of pregnancy and lactation labeling information in prescription drug and biological products as modified under the Pregnancy and Lactation Labeling Rule. The Pregnancy and Lactation Labeling Rule (PLLR) was implemented in June 2015, and required changes to labeling of information in prescription drug and biological products to better communicate clinically relevant information to health care providers on risks associated with medication exposure during pregnancy and lactation.

The agency generally sought input and recommendations on:

- How information in PLLR labeling is being perceived and used by health care providers and other stakeholders;
- Factors that are critical to health care providers' interpretation of the data and counseling of pregnant women on the risks and benefits of a medication; and
- How to convey risk information to health care providers to accurately and adequately inform risk-benefit considerations for medication use during pregnancy.

Meeting Materials

Prior to the meeting, FDA provided a background packet to brief the committee members. The packet is posted to the FDA website at FDA Briefing Document for the March 5-6, 2018 Risk Communication Advisory Committee Meeting.

A full list of meeting participants and affiliations can be found in the meeting roster.

Full presentation slide decks are available and divided between FDA presentations and invited, non-FDA generated presentations.

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Day One, Mar 5, 2018

Chair Blalock called the meeting to order and Lee Zwanziger read the conflict of interest statement. The committee then listened to presentations from FDA and invited speakers and one open public hearing speaker.

FDA PRESENTATIONS

Opening Remarks	**Malcolm J. Bertoni, M.S.** FDA
Welcome / Opening Remarks	**Lynne P. Yao, M.D.** FDA
An Evolution of Labeling Information for Pregnant Women: PLLR History and Background	**Catherine Roca, M.D.** FDA
Fulfilling the Intent of PLLR: Current Approaches and Challenges	**Leyla Sahin, M.D.** FDA

GUEST SPEAKER PRESENTATIONS

Physicians' Perspective of the New Pregnancy and Lactation Labeling: Survey Results	**Jennifer A. Namazy, M.D.** Scripps Clinic Medical Group
Communicating Risk in an Environment of Uncertainty	**Michael F. Greene, M.D.** Representative, The American College of Obstetricians and Gynecologists Harvard Medical School Massachusetts General Hospital
Prescribing for Pregnant Psychiatric Patients: Progress Report	**Katherine L. Wisner, M.S., M.D.** Northwestern University
Communication: Advisory Committee on Immunization Practices (ACIP) Recommendations and Vaccine Uptake by Pregnant Women	**Laura E. Riley, M.D.** Harvard Medical School Massachusetts General Hospital

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Communicating Teratogen Information Effectively: The Teratogen Information Service (TIS) Perspective	**Elizabeth Conover, M.S., APRN** University of Nebraska Medical Center
A Patient Perspective: Pregnancy and Lactation Labeling Rule - A Modern Day Medical X Factor	**Jamie Zahlaway Belsito** Effie's Grace, LLC
Pregnancy and Lactation Labeling: A Law and Ethics Perspective	**Kayte Spector-Bagdady, J.D., MBioethics** University of Michigan
Pregnancy and Lactation Labeling Rule (PLLR) from an Industry Perspective	**Traci J. Lee, Pharm.D.** GlaxoSmithKline
Charge to Committee/Committee Discussion	**Jodi Duckhorn** FDA
Adjournment	**Susan J. Blalock, Ph.D., M.P.H.** Chair Risk Communication Advisory Committee

Day Two, March 6, 2018

Dr. Blalock opened the meeting and Lee Zwanziger read the conflict of interest statement. There were no open public hearing speakers.

The committee discussed the questions.

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Questions to Committee

The table below lists the questions for committee discussion and where to find each discussion in the transcript or recording.

Question One Discuss how the factors below impact healthcare provider decision-making and patient counseling. A. Risk perception B. Interpretation of uncertainties of available data on drug use in pregnant women C. Context of drug-associated risks in relation to the background risk information on major birth defects and miscarriage D. Benefit-risk considerations E. Medicolegal considerations	Transcript Pages 250-339 Webcast Recording - Question One, Mar 5 Webcast Recording - Question One, Mar 6
Question Two A. Discuss how effective PLLR has been in conveying safety evidence in pregnancy that is useful to benefit-risk decision making. Include in your discussion the following: i. Interpretability of safety evidence in drug labeling ii. Interpretability and impact of animal data on decision-making when there are no human data iii. Information that has been unhelpful or has led to unintended adverse consequences (e.g., avoidance of needed treatment) If appropriate, recommend strategies to improve risk communication that comply with PLLR requirements. B. Consider the following situations and discuss best practices to communicate the following in drug	Transcript Pages 339 - 387 Webcast Recording - Question Two

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product labeling, if appropriate: i. Observational study data where inconsistent study findings preclude a clear conclusion ii. Observational study data where the weight of evidence show no increased risk for major malformations, but some data suggest an increased risk iii. Observational study data where there are methodologic limitations (i.e., when to include or not to include these data) iv. When there are no study data, but cases reported in the pharmacovigilance safety database are available	
Question Three A. Discuss your interpretation of the following phrases currently used in the PLLR Risk Summary, and provide any suggestions for improvement, if applicable: "adverse developmental outcome," "limited data," "available data are not sufficient to inform the risk," and "available data have not reported a clear association." B. Discuss how language affects the following: i. Physician willingness to treat pregnant patients ii. Patient decision-making and adherence to treatment iii. Pregnancy planning and prevention (for example, need for pregnancy testing before prescribing a medicine) C. Discuss intended and unintended consequences, including prescriber liability, that may occur with certain language or communication approaches.	Transcript Pages 387 - 408 Webcast Recording - Question Three and Four
Question Four A. Suppose FDA has some evidence of a potential drug safety issue for pregnant women, but the	Transcript Pages 408 - 437 Webcast Recording - Question

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evidence is limited and preliminary. What should FDA consider in deciding when and how much to communicate to the public about what it does and doesn't know? And what should FDA consider in deciding whether to wait? B. Suppose FDA has determined that communication about the potential for adverse effects in pregnancy is necessary. What additional comments do you have about how FDA can communicate to maintain a balanced assessment of the benefit and risk, and to minimize unintended adverse consequences?	Three and Four

Dr. Blalock adjourned the meeting.

Panel Members in Attendance

SUSAN J. BLALOCK, Ph.D., M.P.H.	Chair
CYNTHIA BAUR, Ph.D.	Member
DAVID M. BERUBE, Ph.D.	Member
JOSEPH N. CAPPELLA, Ph.D.	Member
W. TIMOTHY COOMBS, Ph.D.	Member
NATHAN F. DIECKMANN, Ph.D.	Member
ELIZABETH HOWLETT, Ph.D.	Member
GARY L. KREPS, Ph.D.	Member
CHARLES LEE, M.D.	Member
ANDREW PLEASANT, Ph.D.	Member
RAJIV N. RIMAL, M.A., Ph.D.	Member

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PAUL SLOVIC, Ph.D.	Member
JEANNIE SNEED, RD, Ph.D.	Member
MICHAEL S. WOLF, M.A., M.P.H., Ph.D.	Member
MYLA GOLDMAN, M.D.	Temporary Member
ANNE LYERLY, M.A., M.D.	Temporary Member
CATHERINE SPONG, M.D.	Temporary Member
JAMES TRACY, D.O.	Temporary Member
ALMUT WINTERSTEIN, RPh, Ph.D., FISPE	Temporary Member
ELIZABETH A. JONIAK-GRANT, Ph.D.	Patient Representative
GERARD NAHUM, M.D., FACOG	Industry Representative
SUZANNE B. ROBOTTI	Consumer Representative
LEE ZWANZIGER, Ph.D.	Designated Federal Officer

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