Meeting of the Risk Communication Advisory Committee

March 5-6, 2018

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

Points for Advisory Committee Discussion

FDA seeks input from the Risk Communication Advisory Committee on the following discussion points:

1. 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

2. 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 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

Points for Advisory Committee Discussion (cont.)

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

3. 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.

4. A. Suppose FDA has some evidence of a potential drug safety issue for pregnant women, but the 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?