Evaluation of the Safety of Drugs and Biological Products used during Lactation

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Disclosure Statement

• I am employed by the US Food and Drug Administration and I have no financial relationships to disclose relating to this presentation.

• The views expressed in this talk represent my opinions and do not necessarily represent the views of FDA.
Mrs. Winslow’s Soothing Syrup claimed to help babies with teething pain.

The syrup was laced with morphine, a narcotic.

The label did not include morphine as an ingredient.

Many infants died as a result.
A Brief History

• **Pure Food and Drugs Act**
  – Passed by Congress in 1906
  – Labeling of drugs must clearly state all ingredients
  – Created the US FDA

• **Food, Drug, and Cosmetic Act**
  – Passed by Congress on June 25, 1938 after tragedy of Sulfanilamide
  – A manufacturer of a drug must prove to FDA that their *drug is safe* before it can be sold

• **Kefauver-Harris Drug Amendments**
  – Signed into law by President John F. Kennedy in 1962 after tragedy of Thalidomide
  – A manufacturer of a drug must prove to FDA that their *drug is effective* before it can be sold
A Brief History

• Pregnancy and Lactation
  – First labeling requirements published 1979 and include Pregnancy Letter Category
  – Public hearing to discuss improvements in labeling in 1997

• Draft Guidance on clinical lactation studies and recommendations for labeling published in 2005

• Pediatric Advisory Committee convened to discuss clinical lactation studies in 2007

• Proposed Pregnancy and Lactation Labeling Rule published in 2008

• Final Pregnancy and Lactation Labeling Rule published December 3, 2015
Goals of the Workshop

• Review current approaches to the collection of data when drugs are used or expected to be used during lactation
• Discuss and consider novel approaches to improve the quality and quantity of data to inform about potential risks of medication use during lactation
• Raise awareness and engage stakeholders about communication of safety information related to maternal use of medications during lactation
Agenda

• Day 1 of the workshop
  – Review and discuss current approaches for the collection of data
  – Review and discuss gaps in our present knowledge
  – Review and discuss strategies to communicate safety information related to maternal use of medications during lactation

• Day 2 of the workshop
  – Discuss novel approaches to improve the quality and quantity of data available to assess the safety of medications used during lactation