



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- Draft Guidance on clinical lactation studies and recommendations for labeling published in 2005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