The opinions shared in this presentation are those of the presenter and should not be interpreted as the position of the US Food and Drug Administration.
Fetal Pharmacology has a history tied to developmental pharmacology

Dr. Sumner Yaffe: The Father of Pediatric Clinical Pharmacology

- Stanford, Director of the Clinical Research Center for Premature Infants
- Developed Pediatric Clin Pharm programs at Buffalo Children’s Hospital
- At Buffalo, collaborated with Dr.’s Gary Levy and Bill Jusko, and incorporated pharmacokinetics into pediatric clinical pharmacology studies.

- Director of the Center for Research for Mothers and Children at the National Institute of Child Health and Human Development, National Institutes of Health

1923-2011

Dr. Yaffe had a special focus on fetal and perinatal pharmacology
Established Fetal Pharmacology as a Critical Area of Study

SOME ASPECTS OF PERINATAL PHARMACOLOGY¹,²

By Sumner J. Yaffe, M. D.
Department of Pediatrics, School of Medicine, State University of New York at Buffalo, Buffalo, New York

- Annual Review of Medicine. 17:213-34, 1966
- “The administration of a drug to a pregnant woman presents a unique problem to the physician; not only must he consider maternal pharmacologic mechanisms, but he must also be aware of the fetus as a potential recipient of the drug.”
- “It is clear that many areas for future investigation remain. Hopefully, the descriptive phase of research will be supplanted by a more sophisticated molecular approach. Only in this way will drug administration during the perinatal period truly represent optimal therapeusis instead of dogmatic posology, and contributions to a better understanding of developmental physiology be made.”
Dr. Yaffe knew what was needed

• More sophisticated studies of drug concentrations in the mother, fetus and newborn (work with Dr’s Gary Levy and Bill Jusko);
• Placental metabolism and transfer studies (1969);
• Drug disposition in the fetus (1968);
• More sophisticated fetal toxicity studies (1968-1975);
• Drug metabolism studies (1968-1970);
• Ethical considerations (1975).
Dr.’s Yaffe and Giacoia continued this work at NICHD

Obstetric and Fetal Pharmacology

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273 references
Today’s Workshop

• We get to see the continuation of work started 55 years ago!

• Many thanks to:
  – Un. of Maryland CERSI (Dr.’s Jill Morgan, James Polli and Ann Anonsen)

  – The Organizing Committee: Dr.’s Dionna Green, Andre Dallmann (Bayer), Jill Morgan, K. Park, Varsha Mehta, William Slikker, Gerri Baer, Bob Ward (Un. Utah) and Larissa Laptiva and CBER colleagues.
Agenda

• Thursday, Oct. 21 (10:00 am – 3:00 pm ET)
  – Introductory session
  – Fetal Safety Studies
  – Fetal Therapeutics

• Friday, October 22 (10:00 am – 2:00 pm ET)
  – Maternal-fetal modeling and simulation
  – M&S Case studies
  – Regulatory perspective