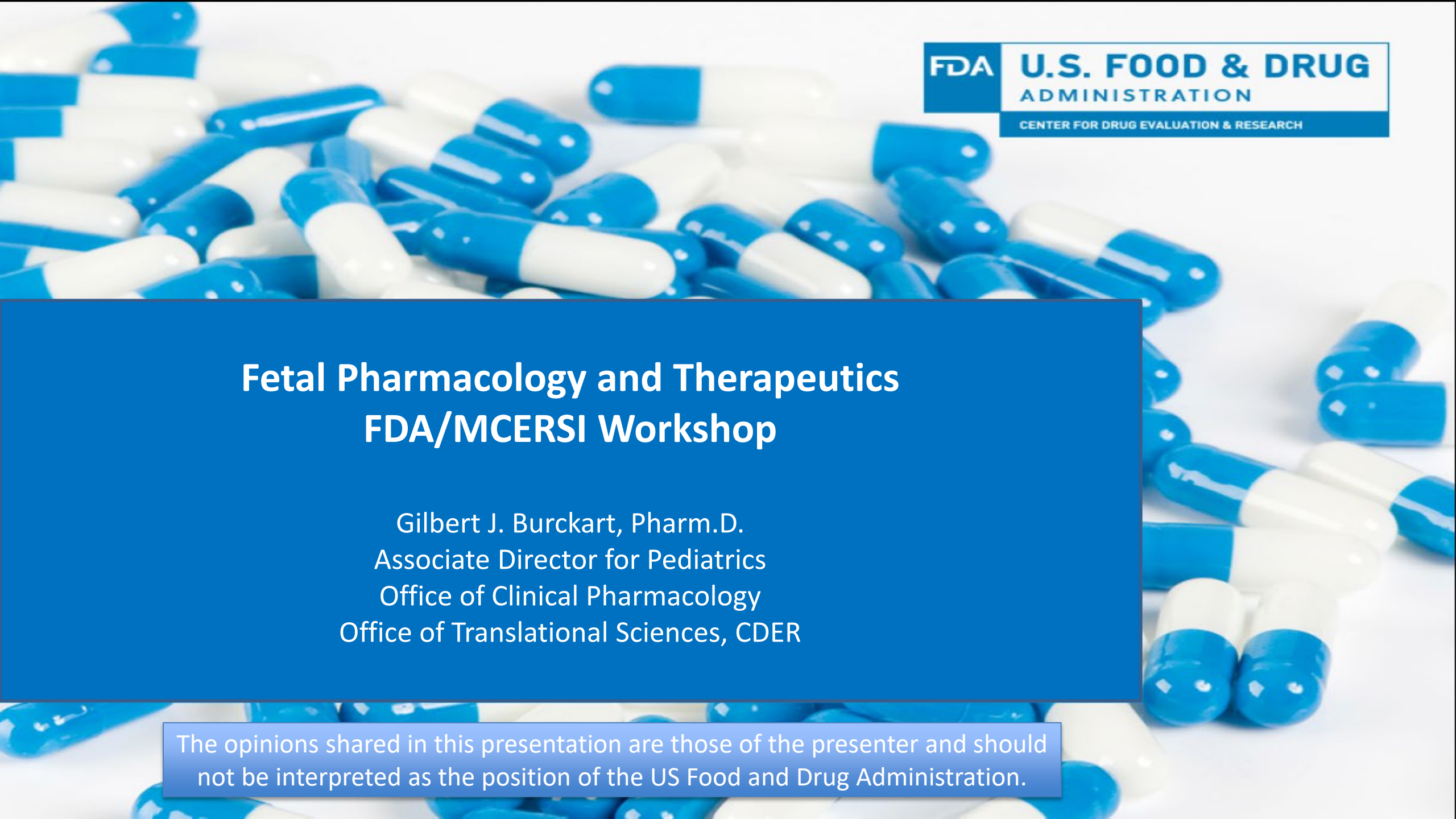


FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH

Fetal Pharmacology and Therapeutics
FDA/MCERSI Workshop

Gilbert J. Burckart, Pharm.D.
Associate Director for Pediatrics
Office of Clinical Pharmacology
Office of Translational Sciences, CDER

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

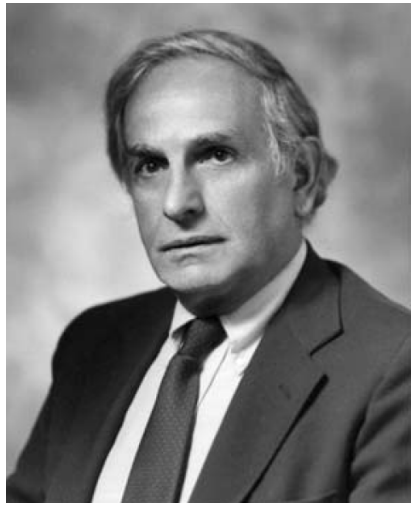
Dr. Sumner Yaffe: The Father of Pediatric Clinical Pharmacology

1923-2011

-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**

Dr. Yaffe had a special focus on fetal and perinatal pharmacology

Established Fetal Pharmacology as a Critical Area of Study



SOME ASPECTS OF PERINATAL PHARMACOLOGY[1,2]

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

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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