

FDA Genetic Toxicology Workshop
**How many doses of an Ames-positive/Mutagenic (DNA Reactive) Drug can be
safely administered to Healthy Subjects?**

November 4, 2019

FDA White Oak Campus – Building 2 (CSU), Room 2031

8:00 – 8:30 a.m. Registration

Presentations

8:30 – 9:00 a.m. Introduction: How many doses of an Ames-Positive (DNA Reactive) Drug can
be safely administered to Healthy Subjects?
Dr. Timothy W. Robison, CDER, FDA

9:00 – 9:25 a.m. FDA Requirements for the Protection of Healthy Subjects in Phase 1 Clinical
Trials
Dr. Kevin Prohaska, CDER, FDA

9:30 – 9:50 a.m. Considerations for a Genotoxic API in Clinical Trials: Healthy Subjects or
Patients?
Dr. Bob Dorsam, CDER, Office of Generics, FDA

9:50 – 10:35 a.m. Literature review for data relevant to administering one or a few doses of a
DNA reactive drug to healthy subjects
Drs. Dayton Petibone and Jennifer Shemansky, NCTR, FDA

10:35 – 10:50 a.m. **Break**

10:50 – 11:25 a.m. Do the Steps between Genotoxin and Cancer Create Thresholds of Dose or
Time?
Dr. Douglas Brash, Yale University

11:25 a.m. – Noon Setting Allowable Exposures to Ames-positive Candidate Drugs
Dr. Kenny Crump, Louisiana Tech University

12:00 – 1:00 p.m. **LUNCH**

Panel Discussion

1:00 – 4:00 p.m.

Moderator

Dr. Aisar Atrakchi
CDER, FDA

Panelists

- Dr. Alan Boobis
Professor of Toxicology (emeritus), Imperial College London
- Dr. Douglas Brash
Professor of Therapeutic Radiology and Dermatology, Yale University
- Dr. Kenny Crump
Professor of Mathematics and Statistics, Louisiana Tech University
- Dr. Robert Heflich
Director, Division of Genetic and Molecular Toxicology
National Center for Toxicologic Research, FDA
- Dr. Timothy McGovern
Office of Drug Evaluation, Associate Director of Pharmacology and
Toxicology, CDER, FDA
- Dr. Miriam C. Poirier
Scientist Emeritus, National Cancer Institute, NIH
- Dr. Kevin A. Prohaska
Captain (U.S. Public Health Service Corps):
Senior Medical Policy Advisor/Bioethics Consultant, FDA
- Dr. Errol Zeiger
Private Consultant/Formerly of the National Toxicology Program

4:00 p.m.

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