

# Biochemical Toxicology

NCTR's Division of Biochemical Toxicology (DBT) conducts fundamental and applied research designed to define the biological mechanisms of action underlying the toxicity of FDA-regulated products, as well as characterizes the carcinogenic risks associated with chemicals of interest to the FDA.

## 2023 Select DBT Accomplishments

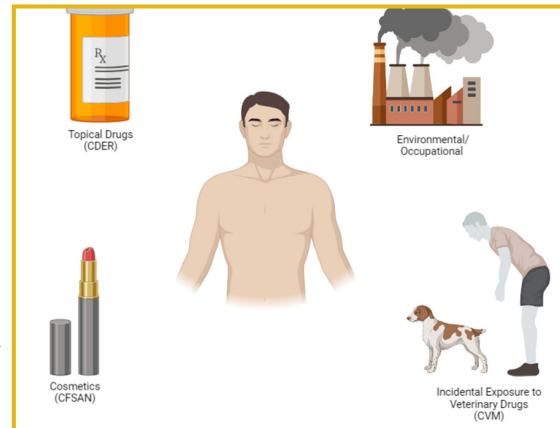
### *The Toxicity of Triclosan*

DBT scientists completed a two-year mouse bioassay elucidating the chronic dermal toxicity/carcinogenicity of triclosan. Triclosan is a widely used bacteriostatic and bactericidal agent that is present in a variety of personal care, consumer, and industrial products. Due to its extensive use, there is potential for humans in all age groups to receive lifetime exposures to triclosan, yet data on the chronic dermal toxicity/carcinogenicity of triclosan were lacking. This research, funded by an interagency agreement between FDA and the National Institute of Environmental Health Sciences, helped address a data gap identified by FDA to assess the risk to humans from dermal exposure to triclosan and contributed to the understanding of the mechanisms of triclosan-associated toxicities. The study findings were reported in [Arch Toxicol](#).

### *Skin Permeation Study of FDA-Regulated Products*

Skin permeation is a primary consideration in the safety assessment of cosmetic ingredients, topical drugs, and human users handling veterinary medicinal products. As the need for dermal absorption studies in dermatological product safety assessments grows, so does the impetus to reduce, refine, and replace the use of animals in regulatory science. Researchers from NCTR's DBT, in collaboration with scientists from FDA's Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition, and Center for Veterinary Medicine, the National Center for Advancing Translational Sciences, and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods, developed a standardized method to evaluate the suitability

of alternative skin barrier models to predict skin absorption in humans. This novel multiparametric experimental approach has broad adaptability to enable the evaluation of existing and future alternative skin barrier models. This work was published in [Toxicol in Vitro](#) and was sponsored by an FDA Chief Scientist Challenge Grant.



### *Breakthrough in the Study of Nonalcoholic Fatty Liver Disease*

Nonalcoholic fatty liver disease (NAFLD) has grown in global frequency to become the most common chronic liver disease, with a prevalence ranging from 25% to 48% in adults and from 8% to 12% in children. Current evidence indicates the existence of substantial interindividual heterogeneity in susceptibility to NAFLD and its severity. NCTR investigators, in collaboration with scientists from FDA's CDER and Texas A&M University, demonstrated that extensive alterations in the expression of disease-related genes are a fundamental feature of the pathogenesis of NAFLD using a genetically diverse Collaborative Cross mouse population. These findings were published in the [Am J Physiol Gastrointest Liver Physiol](#).



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DBT researchers attended Society of Toxicology (SOT) Annual Meeting in March 2023; Left to right: Miao Li, Kiara Fairman, Pavani Gonnabathula, and Me-Kyung (Jennifer) Choi

## 2023 Select DBT Accomplishments (Cont.)

### DBT Research Backs up FDA Regulations

Research conducted by DBT scientists provided important new data to support an [FDA proposal to amend regulations revoking authorization for the use of brominated vegetable oil \(BVO\)](#) in food due to safety concerns. BVO is a food additive used primarily to help emulsify citrus-flavored soft drinks, preventing them from separating during distribution. The rodent safety studies conducted by NCTR were [published in 2022](#) and confirmed previous reports that dietary exposure to BVO is toxic to the thyroid and results in bioaccumulation of lipid-bound bromine in the body at doses relevant to human exposure.

## In 2023, DBT Scientists

In 2023, DBT staff received numerous awards and were invited to participate in the following events:

### Awards

- **FDA Scientific Achievement Award:** [Chief Scientist Publication Award for Translational or Applied Science](#)
- **NCTR Group Recognition Award** for the rapid and thorough review conducted by the NCTR Monograph team in response to the request made by Center for Devices and Radiological Health
- **NCTR Scientific Achievement Award:** [Director's Publication Award for Laboratory Science](#) for assessing male reproductive toxicities induced by cannabidiol and its main metabolites

## In 2023, DBT Scientists (Cont.)

- **Two NCTR Special Act Awards:** For outstanding efforts in ensuring the success of the NCTR Summer Student Research Program (SSRP) and providing mentorship to college students

### Presentations

- SOT 2023 Annual Meeting (17 presentations)
- South-Central Chapter of SOT 2023 Annual Meeting (2 presentations)
- Fall 2023 Tobacco Regulatory Science Meeting (3 presentations)
- FDA Science Forum (3 presentations)
- 9<sup>th</sup> Annual AR-BIC
- 114<sup>th</sup> Annual Meeting of the American Association for Cancer Research
- American College of Clinical Pharmacology Annual Conference
- Arkansas Water Conference
- Chem-Academy Annual Conference on Endocrine Disruptors
- Gordon Research Conference on Barrier Function of Mammalian Skin
- National Capital Area Chapter-SOT and CFSAN Joint Fall 2023 Symposium: Applied Toxicology and Risk Assessment
- Organization for the Study of Sex Differences Annual Meeting

### Other Outreach

- International Agency for Research on Cancer (IARC) Working Group to Evaluate the Carcinogenic Hazards to Humans (aspartame, methyl eugenol, and isoeugenol), Experimental Carcinogenesis Subgroup (chairman)
- IARC Working Group to Evaluate the Carcinogenic Hazards to Humans (perfluorooctanoic acid and perfluorooctanesulfonic acid), Mechanistic Evidence Subgroup (member)
- Office of Equal Employment Opportunity, Diversity & Inclusion Department of Health and Human Services: "Health Disparities in African-American and Minority Communities and Available Resources" (panelist)
- NCTR Summer "Lunch and Learn" Lecture Series for 2023 ORISE SSRP (organizer)
- Pharmacokinetics course at University of North Texas Health Science Center: "Digoxin" and "Obesity" (guest lecturer)
- UAMS Systems Pharmacology and Toxicology (SPaT) T23 Program (invited training faculty staff member)
- UAMS SPaT Workshop: "Radiation Impacts on Toxicity of Cobalt-Chromium Implant Debris" (presenter)

