Activity Outline
FDA Grand Rounds: Bisphenol A: Toxicology and pharmacokinetic data to inform on-going safety assessments
September 13, 2018
WO Bldg 32, Rm 1243

Activity Coordinator
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Series Description
The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description
Bisphenol A (BPA) is a high-production-volume industrial chemical used in the production of polycarbonate plastics and epoxy resins that have broad application in consumer products, including storage containers for foods and beverages, medical devices, and thermal paper. The predominant human exposure is from food containers. Low levels of monomer can migrate from these products and there has been much controversy over the years as to the potential toxicity of this BPA exposure. FDA, under an Interagency Agreement between NCTR and the National Institute of Environmental Health Sciences, has conducted a series of studies over the past decade to address data gaps identified by the FDA Science Board. Pharmacokinetic studies across several species have indicated that BPA undergoes rapid and extensive metabolic inactivation in the gut and liver, with the degree of inactivation in young animals varying across species. FDA scientists developed physiologically based pharmacokinetic models that allow prediction of internal exposures to BPA in target organs of humans across all life stages. Toxicity of BPA was assessed in rats across a broad dose range, from approximately 10-fold to greater than 25,000-fold mean 90th percentile human dietary exposures. For the 2-year toxicology study, animals and tissues were shared with 14 academic laboratories that assessed endpoints not typically included in guideline regulatory studies. The academic results will not be discussed in this presentation, but will be integrated later with the NCTR data. Results of the NCTR toxicity studies indicated that BPA produced adverse effects at high doses, but not at the low end of the dose range tested, consistent with its activity as a weak estrogen. These results will inform on-going BPA safety assessments, a topic of considerable public interest.

References

- Camacho, L., Basavarajappa, M.S., Chang, C.W., Han, T., Kobets, T., Koturbash, I., Surratt, G., Lewis, S.M., Vanlandingham, M.M., Fuscoe, J.C., Gamboa da Costa, G., Pogribny, I.P., Delclos, K.B., 2015. Effects of oral exposure to bisphenol A on gene expression and global genomic DNA methylation in the prostate, female mammary gland, and uterus of NCTR Sprague-Dawley rats. Food Chem Toxicol 81, 92-103.
- Churchwell, M.I., Camacho, L., Vanlandingham, M.M., Twaddle, N.C., Sepehr, E., Delclos, K.B., Fisher, J.W., Doerge, D.R., 2014. Comparison of life-stage-dependent internal dosimetry for bisphenol A, ethinyl estradiol, a reference estrogen, and endogenous estradiol to test an estrogenic mode of action in Sprague Dawley rats. Toxicol Sci 139, 4-20.
- Delclos, K.B., Camacho, L., Lewis, S.M., Vanlandingham, M.M., Latendresse, J.R., Olson, G.R., Davis, K.J., Patton, R.E., Gamboa da Costa, G., Woodling, K.A., Bryant, M.S., Chidambaram, M., Trbojevich, R., Juliar, B.E., Felton, R.P., Thorn, B.T., 2014. Toxicity evaluation of bisphenol A administered by gavage to Sprague Dawley rats from gestation day 6 through postnatal day 90. Toxicol Sci 139, 174-197.
- Doerge, D.R., Twaddle, N.C., Vanlandingham, M., Brown, R.P., Fisher, J.W., 2011. Distribution of bisphenol A into tissues of adult, neonatal, and fetal Sprague-Dawley rats. Toxicol Appl Pharmacol 255, 261-270.

Series Objectives

- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

Learning Objectives After completion of this activity, the participant will be able to:

- Explain the purpose of the BPA research program conducted over the past decade under an Interagency Agreement between FDA and the NIEHS.
- Describe the results of BPA pharmacokinetic studies and explain how these are combined with human exposure data in physiologically based pharmacokinetic models to predict internal exposures to BPA in humans exposed through food contact materials.
- Describe the results of BPA rat toxicology studies conducted over a broad dose range and explain how they can be used in the assessment of BPA safety in humans.

Target Audience
This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 September 13, 2018

Time	Topic	Speaker
12:00 - 1:00 PM	Bisphenol A: Toxicology and pharmacokinetic data to inform on-going safety assessments	Barry Delclos

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This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-18-002-L04-P for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Delclos, Barry, Research Pharmacologist, FDA/NCTR/Division of Biochemical Toxicology - nothing to disclose

Planning Committee

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- KEMPF, LUCAS, MD - nothing to disclose
- Lee, Christine - nothing to disclose
- Wheelock, Leslie, MS, RN, Director, OSPD, FDA, OC, OCS, OSPD - nothing to disclose

CE Consultation and Accreditation Team

- Bryant, Traci, M.A.T., CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.