Evidence-based Toxicology Collaboration Kick-off Meeting[1]

Washington DC, USA, March 10, 2011

The newly organized Evidence-based Toxicology Collaboration (EBTC) held its inaugural conference on March 10, 2011 in Washington DC as a satellite to the 50th Annual Society of Toxicology meeting. The EBTC is a volunteer group of individuals with ties to US governmental agencies, chemical and pharmaceutical companies, academia, and animal protection organizations. The group's purpose is to foster the development of a process, based on the Cochrane Collaboration in Evidence-based Medicine (EBM), for quality assurance of new toxicity tests for the assessment of safety in humans and the environment. (A list of the members of the Steering Committee with their respective organizations appears below.)

At the kick-off meeting, speakers introduced the audience of about 130 attendees to the concept of Evidence-based Medicine and how it might be applied to validating toxicity tests developed under a new paradigm, i.e., the one described in the NRC report *Toxicity Testing in the 21st Century: A Vision and a Strategy* (Tox 21c). Dr. **Milo Puhan**, a member of the Cochrane Collaboration, made the first presentation, describing the concept of Evidence-based Medicine and the methodologies used to conduct systematic reviews of the literature to produce reference documents for clinicians. The Cochrane Collaboration is housed at the Johns Hopkins Bloomberg School of Public Health.

Dr. **Thomas Hartung**, Director of the Johns Hopkins Center for Alternatives to Animal Testing (CAAT), then provided a history of the Evidence-based Toxicology idea and how such an approach might be well suited to evaluating the quality of new tests for safety assessment. Dr. **Kim Boekelheide**, a member of the NRC committee that wrote the Tox 21c report, gave a case study using carcinogenicity and genotoxicity testing in animals as an example of how inappropriate the current animal tests are for predicting human carcinogens; in fact, the animal tests have not been validated against known human carcinogens. These presentations established the basis for developing new validation methods for new toxicological tools that are based on mechanistic toxicology and on discovering pathways of toxicity in humans.

Two representatives of US regulatory agencies and two representatives from regulated industries gave the final set of presentations in the session. Dr. **Suzanne Fitzpatrick** from the Food and Drug Administration and Dr. **Jack Fowle** from the Environmental Protection Agency spoke about the willingness of their respective agencies to work with the industries and academic scientists to help incorporate the new testing strategies into the regulatory process. Two representatives from regulated industries, Dr. **Robert Chapin** from Pfizer and Dr. **Fran Kruszewski** from the American Cleaning Institute, speaking for the chemical industry, addressed the needs of their respective industries vis-à-vis the types of tests that would be useful and necessary for the evaluation of new drugs and chemicals, respectively.

The meeting closed with a discussion session in which audience members asked the panel questions about the presentations and about how to move forward in the process. Dr. Hartung indicated that the Center for Alternatives to Animals Testing will serve as secretariat for the EBTC and will work with the Steering Committee to develop the next steps. The first of these steps is to identify individuals interested in playing a role in writing the procedural guidelines for the entire EBT enterprise. Until such guidelines are established, the Steering Committee will assume the role of appointing experts to working groups that will address methods development, guidelines for conducting systematic reviews, etc.

A full conference/workshop will be planned for the fall of 2011.

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The EBTC Steering Committee (and their organizations[2])

Melvin Andersen, The Hamner Institute
Richard Becker, American Chemical Council
Kim Boekelheide, Brown University
James Bus, Dow Chemical Company
Robert Chapin, Pfizer
Rodger Curren, Institute for In Vitro Sciences
Suzanne Fitzpatrick, US FDA
Jack Fowle, US EPA
Alan Goldberg, JHU CAAT
Thomas Hartung, JHU CAAT
Michael Holsapple, ILSI/HESI
Wendolyn Jones, CropLife America
Richard Judson, US EPA
Fran Kruszewski, American Cleaning Institute
Martin Stephens, Humane Society of the US
William Stokes, NIEHS, NIH
Raymond Tice, National Toxicology Program
Mark Vossenar, Agilent Corp.
Neil Wilcox, US FDA
Joanne Zurlo, JHU CAAT

[1] Sponsors of the meeting included CAAT, the Society of Toxicology, the American Chemistry Council, the American Cleaning Institute, and CropLife America.

[2] N.B. Organizations are listed for identification purposes only and should not be construed as their endorsement of this activity.