



# EMERGING SCIENCE FOR ENVIRONMENTAL HEALTH DECISIONS

## AGENDA

### ● Predicting Human Health Effects from Environmental Exposures: Applying Translatable and Accessible Biomarkers of Effect

AUGUST 12-13, 2020

THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE

ALL TIMES LISTED ARE EASTERN DAYLIGHT TIME

A VIRTUAL WORKSHOP

BIOMARKERS OF EFFECT ARE MEASURABLE changes in an organism that serve as indicators of health impairment or disease. While biomarkers have been a cornerstone of medical practice, researchers have recently identified a variety of new biomarkers that signal conditions such as organ system damage, Alzheimer's disease, and cancer. There is potential to use these new biomarkers to measure adverse health effects that may arise due to exposure to environmental pollutants.

This virtual workshop will mine emerging knowledge from model systems and clinical studies to explore how biomarker approaches can be applied to understanding the consequences of

environmental exposures, and thus improve environmental health decisions.

Speakers will emphasize biomarkers of immunity and autoimmunity, neurological, carcinogenic, and epigenetic effects, and how to apply new biomarkers to environmental health decision-making, keeping in view judicious and equitable deployment of biomarker strategies for health surveillance across diverse populations.

The scientific presentations at this workshop will be pre-recorded and released on August 3. Workshop participants will come together for online discussions and brainstorming sessions on August 12-13.

#### PRE-RECORDED PRESENTATIONS

##### NEW HORIZONS FOR BIOMARKERS OF EFFECT

*Beginning August 3, the following pre-recorded presentations will be available to view at <https://bit.ly/esehdbiomarkers>. Workshop registrants will receive a link to an online collaborative workspace that will serve as the venue for asking questions during the workshop's discussion panels.*

- Characteristics of a Robust Biomarker of Effect: Lessons Learned from Development of KIM-1 Biomarker for Kidney Injury—**John-Michael Sauer**, Critical Path Institute

- Identifying Epigenetic Biomarkers of Arsenic-Induced Fetal Birthweight—**Rebecca Fry**, University of North Carolina, Chapel Hill
- Biomarkers of Immunotoxicity and Applicability to PFAS and Other Environmental Toxicants—**Jamie DeWitt**, East Carolina University
- Biomarkers of Autoimmunity: Collaborations with Metals Mixture-Exposed Communities—**Esther Erdei**, University of New Mexico

(continued)

The National Academies of  
SCIENCES • ENGINEERING • MEDICINE

Register at  
<https://bit.ly/esehdbiomarkers>

## PRE-RECORDED PRESENTATIONS (CONTINUED)

- Development, Validation and Application of an in vitro Transcriptomic Biomarker for Genotoxicity Testing—**Carole Yauk**, University of Ottawa
- New Biomarker for Genotoxicity Mode of Action Determination—**Marc Audebert**, Toxalim, Université de Toulouse
- Developing Fluidic Biomarkers of Central Nervous System Damage—**Syed Imam**, U.S. Food and Drug Administration
- TSPO: A Biomarker of Brain & Peripheral Inflammation—**Tomás Guilarte**, Florida International University

## WEDNESDAY, AUGUST 12 10:00 AM-2:00 PM

10:00 Welcome and Opening Remarks

- **Keegan Sawyer**, National Academies of Sciences, Engineering, and Medicine
- **Rick Woychik**, National Institute of Environmental Health Sciences
- **Kim Boekelheide**<sup>\*§</sup>, Brown University

### SESSION 1 THE ROLE OF EMERGING METHODOLOGIES AND TECHNOLOGIES IN BIOMARKER DISCOVERY AND TRANSLATION

10:20 The Importance and Promise of Biomarkers of Effect in Environmental Health—**Nicole Deziel**<sup>\*§</sup>, Yale University & **Patrick McMullen**<sup>\*§</sup>, ScitoVation

10:40 Biomarkers of Effect Use in Environmental Health Research and Decision Making: MicroRNAs as an Example—**Brian Chorley**, U.S. Environmental Protection Agency

11:05 Panel Discussion

<sup>\*</sup> Member of the Workshop Organizing Committee for Predicting Human Health Effects from Environmental Exposures: Applying Translatable and Accessible Biomarkers of Effect

<sup>§</sup> Member of the Standing Committee on the Use of Emerging Science for Environmental Health Decisions

**Moderator: Norbert Kaminski**<sup>\*§</sup>, Michigan State University

- **Marc Audebert**, Université de Toulouse
- **Rebecca Fry**, University of North Carolina, Chapel Hill
- **Tomás Guilarte**, Florida International University
- **Syed Imam**, U.S. Food and Drug Administration
- **Sybil Pettit**, Health and Environmental Sciences Institute

11:50 Break

### SESSION 2 DATA RELIABILITY AND TRANSPARENCY CONSIDERATIONS IN DECISION-MAKING PROCESSES

12:30 Evaluating and Improving the Biomarker Pipeline—**Joshua Wallach**, Yale University

12:55 Panel Discussion

**Moderator: William Mattes**<sup>\*</sup>, U.S. Food and Drug Administration

- **Sarah Blossom**, Arkansas Children's Research Institute
- **Jamie DeWitt**, East Carolina University
- **Christina Jones**, National Institute of Standards and Technology
- **John-Michael Sauer**, Critical Path Institute
- **Joshua Wallach**, Yale University
- **Carole Yauk**, University of Ottawa

1:50 Day 1 Closing Remarks—**Gary Ginsberg**<sup>\*§</sup>, New York State Department of Health

2:00 Adjourn Day 1

## THURSDAY, AUGUST 13 10:00 AM-2:30 PM

10:00 Day 2 Welcome and Opening Remarks—**Lesa Aylward**<sup>\*§</sup>, Summit Toxicology

(continued)

## THURSDAY, AUGUST 13 (CONTINUED)

### SESSION 3 ADDRESSING POPULATION VARIABILITY AND DIVERSITY

10:10 Inclusive Science: Developing Population Relevant Biomarkers of Effect—**Chandra Jackson**, National Institute of Environmental Health Sciences

10:35 Panel Discussion

**Moderator: Alison Harrill\***, National Institute of Environmental Health Sciences

- **Andres Cardenas**, University of California, Berkeley
- **Brian Chorley**, U.S. Environmental Protection Agency
- **Esther Erdei**, University of New Mexico
- **Rebecca Fry**, University of North Carolina, Chapel Hill
- **Chandra Jackson**, National Institute of Environmental Health Sciences
- **Lesliam Quirós-Alcalá**, Johns Hopkins University

11:30 Break

### SESSION 4 DETERMINING THE READINESS OF AN EMERGING BIOMARKER OF EFFECT FOR USE IN ENVIRONMENTAL HEALTH DECISIONS: CONCURRENT BREAKOUT DISCUSSION & DEBATE

12:00 Overview of the Brainstorming Activity – Debating the Readiness of the Biomarker of Effect  $\gamma$ H2AX—**Patrick McMullen\***, ScitoVation

12:15 Concurrent Breakout Discussions

*Prompt 1:  $\gamma$ H2AX measurement in a panel of human cells should be added to the standard FDA genotoxicity battery.*

\* Member of the Workshop Organizing Committee for Predicting Human Health Effects from Environmental Exposures: Applying Translatable and Accessible Biomarkers of Effect

§ Member of the Standing Committee on the Use of Emerging Science for Environmental Health Decisions (ESEHD)

† Member of the ESEHD Federal Government Liason Group

### Breakout Group A – Pro: $\gamma$ H2AX is Ready For Use in Risk Assessment

- **Lesa Aylward\***, Summit Technology
- **Marc Audebert**, Université de Toulouse
- **Stephen Dertinger**, Litron Labs
- **Rebecca Fry**, University of North Carolina, Chapel Hill
- **Jamie DeWitt**, East Carolina University
- **Norbert Kaminski\***, Michigan State University
- **John-Michael Sauer**, Critical Path Institute

### Breakout Group B – Con: $\gamma$ H2AX is Not Ready For Use in Risk Assessment

- **William Mattes\***, U.S. Food and Drug Administration
- **Syed Imam**, U.S. Food and Drug Administration
- **Patrick McMullen\***, ScitoVation
- **Les Recio**, Integrated Laboratory Systems
- **Rita Schoeny**, Independent Consultant
- **Carole Yauk**, University of Ottawa

*Prompt 2: The  $\gamma$ H2AX biomarker is sufficiently developed that it could be used for monitoring potential effects in workers.*

### Breakout Group C – Pro: $\gamma$ H2AX is Ready for Use to Screen/Monitor At-Risk Populations

- **Alison Harrill**, National Institute of Environmental Health Sciences
- **Kim Boekelheide\***, Brown University
- **Esther Erdei**, University of New Mexico
- **David Gerhold†**, National Center for Advancing Translational Sciences
- **Gina Solomon**, University of California, San Francisco
- **Reza Rasoulpour§**, Corteva Agriscience

### Breakout Group D – Con: $\gamma$ H2AX is Not Ready for Use to Screen/Monitor At-Risk Populations

- **Nicole Deziel\***, Yale University
- **Sarah Blossom**, Arkansas Children's Research Institute

(continued)

## THURSDAY, AUGUST 13 (CONTINUED)

- **Brian Chorley**, U.S. Environmental Protection Agency
- **Gary Ginsberg**<sup>\*§</sup>, New York State Department of Health
- **Robert Heflich**, National Center for Toxicological Research
- **Mark Johnson**, U.S. Army Public Health Center

- 1:05 Break
- 1:15 Report-Outs and Discussion: Pros and Cons on the Use of Emerging Biomarkers of Effect
- 2:10 Closing Remarks—**Kim Boekelheide**<sup>\*§</sup>, Brown University
- 2:30 Adjourn Workshop<sup>‡</sup>

\* Member of the Workshop Organizing Committee for Predicting Human Health Effects from Environmental Exposures: Applying Translatable and Accessible Biomarkers of Effect

§ Member of the Standing Committee on the Use of Emerging Science for Environmental Health Decisions (ESEHD)

‡ The Use of Emerging Science for Environmental Health Decisions Committee Business Meeting is from 2:45–3:30 p.m. This meeting is open to committee members, government liaisons, and workshop participants.

### Workshop Organizing Committee

This workshop was organized by the following experts: **Lesa Aylward**<sup>§</sup>, Summit Toxicology; **Kim Boekelheide**<sup>§</sup>, Brown University; **Nicole Deziel**<sup>§</sup>, Yale University; **Gary Ginsberg**<sup>§</sup>, NY Department of Health; **Alison Harrill**, National Institute of Environmental Health; **Nobert Kaminski**<sup>§</sup>, Michigan State University; **William Mattes**, US Food and Drug Administration; **Patrick McMullen**<sup>§</sup>, ScitoVation

### About the Use of Emerging Science for Environmental Health Decisions

The National Academies' Standing Committee on the Use of Emerging Science for Environmental Health Decisions (ESEHD) examines and discusses issues on the use of new science, tools, and research methodologies for environmental health decisions.

The ESEHD committee is organized under the auspices of Board on Life Sciences and the Board on Environmental Studies and Toxicology of the National Academies of Sciences, Engineering, and Medicine, and sponsored by the National Institute of Environmental Health Sciences.

