

supplemental data, there are expanded opportunities for researchers to disseminate actual study data; this should facilitate independent evaluation by regulatory agencies.

As scientists specializing in regulatory safety evaluations, we have extensive experience in interpreting chemical toxicity studies from government, academia, and private-sector laboratories. In conducting chemical risk assessments, we believe that scientists from all sectors should support the use of objective criteria for determining data quality and study reliability (Schneider et al. 2009) coupled with a structured evaluative framework, such as that of the World Health Organization International Programme on Chemical Safety (Boobis et al. 2006, 2008), to provide a systematic approach for assessing the overall weight of the evidence for observed effects and the postulated mode of action. In this manner, data from laboratory experiments, epidemiological investigations, and cutting-edge mechanistic research from all relevant studies—GLP and non-GLP—and from all investigators, regardless of affiliation or funding source, can be comprehensively reviewed, given appropriate weight, and integrated in a manner that provides a robust, biologically plausible understanding of the potential hazards and risks that exposures to a substance could pose.

This letter has been reviewed in accordance with the peer- and administrative-review policies of the authors' organizations. The views expressed here are those of the authors and do not necessarily reflect the opinions and/or policies of their employers.

The authors are employed by trade associations whose members manufacture and use chemicals.

Richard A. Becker

American Chemistry Council
Arlington, Virginia

E-mail: rick_becker@americanchemistry.com

Erik R. Janus

Crop Life America
Washington, DC

Russell D. White

American Petroleum Institute
Washington, DC

Francis H. Kruszewski

Soap and Detergent Association
Washington, DC

Robert E. Brackett

Grocery Manufacturers Association
Washington, DC

REFERENCES

- Barrow CS, Conrad JW Jr. 2006. Assessing the reliability and credibility of industry science and scientists. *Environ Health Perspect* 114:153–155.
- Becker RA, Erik R. Janus ER, White RD, Kruszewski FH, Brackett RF. 2009. Good Laboratory Practices and safety assessments [Letter]. *Environ Health Perspect* 117:A482–A483.
- Boobis AR, Cohen SM, Dellarco V, McGregor, D, Meek, ME, Vickers C, et al. 2006. IPCS Framework for analyzing the

relevance of a cancer mode of action for humans. *Crit Rev Toxicol* 36:781–792.

Boobis AR, Doe JE, Heinrich-Hirsch B, Meek ME, Munn S, Ruchirawat M, et al. 2008. IPCS framework for analyzing the relevance of a noncancer mode of action for humans. *Crit Rev Toxicol* 38:87–96.

Maurissen JP, Gilbert SG, Sander M, Beauchamp TL, Johnson S, Schwetz BA, et al. 2005. Workshop proceedings: managing conflict of interest in science. A little consensus and a lot of controversy. *Toxicol Sci* 87:11–14.

Myers JP, vom Saal FS, Benson T, Akingbemi BT, Arizono K, Belcher S, et al. 2009. Why public health agencies cannot depend on Good Laboratory Practices as a criterion for selecting data: the case of bisphenol A. *Environ Health Perspect* 117:309–315.

Schneider K, Schwarz M, Burkholder I, Kopp-Schneider A, Edle L, Kinsner-Ovaskainen A, et al. 2009. "ToxRTool," a new tool to assess the reliability of toxicological data. *Toxicol Lett* 189:138–144.

Society of Toxicology. 2008. Principles for Research Priorities in Toxicology. Available: <http://www.toxicology.org/ms/PrinResearch.asp> [accessed 12 January 2010].

Tyl RW. 2009. Basic exploratory research versus guideline-compliant studies used for hazard evaluation and risk assessment: bisphenol A as a case study. *Environ Health Perspect* 117:1644–1651.

ICCVAM: Not Doing Enough

doi:10.1289/ehp.1001969

Anyone interested in the facts about the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and its ineffectiveness, rather than just another ICCVAM/National Toxicology Program (NTP) fluff piece (Birnbaum and Stokes 2010), should read the 2008 front page *Washington Post* exposé of ICCVAM (Gaul 2008) and the PETA report on which the *Post* investigation was based (PETA 2008).

Birnbaum and Stokes' "PR piece" notwithstanding, ICCVAM should be held responsible for failing to abide by its Congressional mandate to support the development and implementation of non-animal testing methods.

Sadly, it appears that the new leadership of the National Institute of Environmental Health Sciences is no more inclined to improve the quality of the science supporting regulatory decision-making than the previous one.

The author is employed by People for the Ethical Treatment of Animals, the largest animal rights organization in the world.

Jessica Sandler

Regulatory Testing Division

People for the Ethical Treatment of Animals
Norfolk, Virginia

Email: JessicaS@peta.org

REFERENCES

- Birnbaum LS, Stokes WS. 2010. Safety testing: moving toward alternative methods [Editorial]. *Environ Health Perspect* 118:A12–A13.
- Gaul GM. 2008. In U.S., Few Alternatives to Testing on Animals. *Washington Post*, 12 April. Available: <http://www.washingtonpost.com/wp-dyn/content/article/2008/04/11/AR2008041103733.html> [accessed 19 January 2010].
- PETA. 2008. Regulatory Testing: Why Is the U.S. So Far Behind Europe? Available: <http://blog.peta.org/archives/ICCVAM%20Report%203-25-08.pdf> [accessed 5 April 2010].

ICCVAM: Birnbaum and Stokes Respond

doi:10.1289/ehp.1001969R

Sandler's comments about our editorial concerning the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (Birnbaum and Stokes 2010) suggest a lack of awareness of the role and significance of the contributions of ICCVAM. The 2008 *Washington Post* article she cites (Gaul 2008) contained many inaccurate statements (a letter correcting the errors was submitted to the *Washington Post*, but it was not published). We appreciate this opportunity to provide accurate factual information about ICCVAM.

ICCVAM is a congressionally mandated committee that does not have laboratories and does not develop test methods or conduct validation studies. Rather, ICCVAM depends on other organizations, including its 15 member agencies, to carry out such activities. The director of the National Institute of Environmental Health Sciences (NIEHS) established ICCVAM in 1997, with the cooperation of 14 other agencies, in order to provide a coordinated interagency process to facilitate the regulatory acceptance of scientifically valid alternative methods. As an interagency forum, ICCVAM also coordinates and promotes related issues, including national and international harmonization, guidance on validation studies, and awareness of accepted alternative methods.

ICCVAM was formally established by legislation in 2000 with signing of the ICCVAM Authorization Act of 2000. This law charges ICCVAM to "review and evaluate new or revised or alternative test methods, ... including the coordination of technical reviews of proposed new or revised or alternative test methods" ICCVAM develops and submits recommendations based on its reviews to the Secretary of Health and Human Services for transmittal to federal agencies. Agencies must review the recommendations and respond to ICCVAM within 180 days. ICCVAM has implemented a transparent and scientifically rigorous evaluation process for test methods that has resulted in national and international regulatory acceptance of all recommended test methods. ICCVAM has contributed to the acceptance of 33 alternative test methods, including 17 based on formal comprehensive evaluations (ICCVAM 2010). Recommendations on an additional 4 methods are pending.

The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) administers ICCVAM and provides scientific and operational support for ICCVAM activities. Consistent with the NTP