

March 2, 2011

Linda Birnbaum, Ph.D.
Director, NIEHS and NTP
P.O. Box 12233
Research Triangle Park, NC 27709

Via e-mail to: birnbaum@niehs.nih.gov

Dear Dr. Birnbaum,

For the reasons detailed below, we are requesting the immediate dismissal of Dr. William Stokes as the head of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). It is clear that under his leadership, ICCVAM has not fulfilled its Congressional mandate to facilitate the implementation of non-animal methods among U.S. regulatory agencies and has actually been actively working against its own stated mission.

The longstanding inadequacy of ICCVAM was clearly documented in PETA's 2007 report, *Regulatory Testing: Why the U.S. Is So Far Behind Europe*; in the 2008 front page *Washington Post* exposé of ICCVAM, "In U.S., Few Alternatives to Testing on Animals: Panel Has Produced 4 Options in 10 Years;" and in our 2010 detailed review of the 33 alternative methods for which ICCVAM has inaccurately claimed credit. We provided you with additional detailed information in our May 29, 2009, letter to you (attached).

The ICCVAM Authorization Act of 2000 stipulates that one of the primary purposes of ICCVAM is to "ensure that new and revised test methods are validated to meet the needs of Federal agencies." Yet ICCVAM's activities have been repeatedly unresponsive to agency needs as well as in conflict with Congress' stated goal of modernizing toxicity testing.

The primary agencies to which ICCVAM is relevant are the EPA and FDA, which require and actually carry out regulatory testing, and to a lesser extent OSHA, CSPC, and DOT, which issue labeling restrictions on products. Recent examples of ICCVAM's failure to meet these agencies' needs include the following:

- ICCVAM failed to appropriately review an industry-initiated and sponsored program to use completely non-animal methods for assessing eye irritation for anti-microbial pesticides. In response to ICCVAM's rejection of this approach, the EPA issued its own pilot program accepting data thus generated.
- ICCVAM failed to review any of the methods currently used in the EPA's Endocrine Disruptor Screening Program (EDSP). The EDSP was used as an example of a program that would benefit from the creation of ICCVAM, yet in the subsequent 10 years, ICCVAM did not review a single method that was included in the program. Several of the methods were reviewed through the Organization of Economic Cooperation and Development (OECD), and the EPA carried out its own validation exercises for the rest of the assays. Two non-animal methods that might be applicable to the EDSP were nominated to ICCVAM for review five and seven years ago, respectively, and are still awaiting ICCVAM recommendations. (ICCVAM is holding a peer review panel meeting on the first of these methods later this month.)
- ICCVAM is carrying out an active campaign to prohibit the U.S. from adopting the Globally Harmonized System (GHS) of labeling put forth by the United Nations and the World Health Organization. Adopting GHS for skin and eye irritation would allow for the use of completely non-animal methods to assess skin irritation using methods that were validated for this purpose by



PETA

PEOPLE FOR THE ETHICAL
TREATMENT OF ANIMALS

HEADQUARTERS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
FAX 757-622-0457

2
March 2, 2011
Birnbaum

the European Centre for the Validation of Alternative Methods (ECVAM). OSHA has already agreed to adopt the GHS for skin irritation. Yet the executive director of ICCVAM (who is also the director of the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods, or NICEATM) has decided that the U.S. should not adopt GHS and has been actively campaigning against adoption of GHS despite the fact that this is clearly a regulatory decision outside the purview of ICCVAM or NICEATM. ICCVAM's campaign against GHS also runs counter to OSHA decisions as well as the internal decision processes of both the EPA and the FDA.

- ICCVAM ignored the EPA and FDA nominations for members of ICCVAM's scientific advisory board, the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). At a recent ICCVAM meeting, nominations from the EPA and FDA were ignored; the nominations for new members instead came directly from a list provided by the executive director of ICCVAM and were not subject to review by other members of ICCVAM. As a federal agency, SACATM's formation falls under FACA regulations, which specify the following:

Agency officials, members of Congress, the general public, or professional societies or current and former committee members may nominate potential candidates for membership. Selection of committee members is made based on the FACA's requirements and the potential member's background and qualifications. Final selection is made by the president or heads of agencies.

- ICCVAM's recent review of the local lymph node assay (LLNA) did not include a review of substances that would allow for its use by the FDA for pharmaceutical dermatologic formulations, and the FDA's response to ICCVAM's recommendations stated that the FDA "is eagerly anticipating a battery of *in vitro* tests to assess dermal sensitivity as a screen for human dermal sensitivity." This response points again to a lack of consideration of agency needs in ICCVAM's review of the LLNA.

With the great strides currently being made in the development of non-animal testing methods, combined with the urgent need to put this science to use to protect workers and the public, the demand for rapid and effective validation of alternative methods has never been greater. While ICCVAM has taken seven years to review a single screening method, the EPA ToxCast program currently utilizes more than 500 screening methods. Under current circumstances it would take several millennia for ICCVAM to validate these for regulatory use. ICCVAM could contribute much more effectively than its past record demonstrates; however, it cannot do so under its current leadership. We look forward to a timely and positive response to our request.

Sincerely,

Jessica Sandler, MHS
Senior Director
Regulatory Testing Division

cc: Kathleen Sebelius, Secretary of Health and Human Services

Attachment: May 29, 2009, letter to Birnbaum