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November 30, 2004

The Honorable Michael Leavitt
Administrator
Environmental Protection Agency
Washington, DC 20460

Dear Mr. Leavitt:

We are writing to express our concerns about the Cooperative Research and Development Agreement (CRADA) between the Environmental Protection Agency (EPA) and the American Chemistry Council (ACC) to study children's exposure to chemicals in the home. We are pleased the Agency has decided to postpone this study to further examine the issues that have been raised in recent press accounts. We have a number of concerns about this CRADA and we would like you to provide us with answers to the questions we have about the role of the ACC as a partner in this research.

Unfortunately, research undertaken by EPA has often become the focus of controversy. Allegations of inadequate and biased application of science by EPA are common themes in regulatory disputes. The Agency has taken numerous steps to avoid these disputes through such efforts as the development of its peer review policy and use of its Science Advisory Boards and the National Academy of Sciences. Therefore, it is difficult to understand the rationale behind the Agency's decision to form a partnership with the American Chemistry Council, the trade group representing the chemical industry, on a study to assess exposure of children to chemicals. At a minimum, this partnership creates the perception of bias in the study because of the Council's conflict of interest. Presumably, one of the reasons for your decision to postpone this work was the issue of potential bias and conflict of interest raised in the Washington Post article of October 26 by the public interest community.

There were several other features of the October 26 Post article that drew our attention. The quotations from Dr. Gilman indicating that the ACC funds come with "no strings attached" and that EPA is in control of the project are not consistent with our reading of the agreement. There are several features of the CRADA and its attached Statement of Work to indicate this statement does not accurately describe ACC's role in the project.

Page 3, Article 2.2 of the CRADA states: "The Council shall have exclusive control and supervision over the conduct of all cooperative research and development work conducted at Council facilities." What analyses are to be performed by Council personnel at Council facilities? Will any of the work performed by Council personnel at Council facilities include analysis of urine or blood samples collected from the participants?

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Page 3, Article 2.3 of the CRADA states: "Project Managers shall be responsible for the overall direction of the work, establishing budgets and providing such approvals and consents as are required hereunder. Principal investigators shall be responsible for the scientific and technical conduct of the work including the exchange of Subject Data and other information." Dr. Tina Bahadori, an employee of the Council, is named as both a Project Manager and a Principal Investigator of the study.

The CRADA text suggests that she will be an equal partner in determining the direction of the work and that the project is not solely under the direction of the EPA Project Manager and Principal Investigator. It therefore appears the Council will hold sway over the direction of the research as the study progresses including input to the possible change in direction of the research if justified by preliminary analyses of the research data. It is also unclear if the Council's role is limited to the study of phthalates, brominated flame retardants, and perfluorinated compounds. The same human subjects, data collection methods, and a number of the samples will be used for both the pesticide and the consumer product chemical studies. Is the Council's role restricted to data collection and analyses of phthalates, brominated flame retardants, and perfluorinated compounds?

Page 4, Articles 3.1 and 3.2 state EPA will provide progress reports and abstracts to the Council for the duration of the project and a final report to the Council of EPA's results six months after the completion of the study. Is it EPA's intention to make these progress and final reports publicly available documents or is the Council provided data and results of the study prior to their public release? As a result of their collaboration and funding to EPA, will the Council be provided data and supporting information on this study that would not otherwise be available to them (or any other outside group) without submitting a successful request under the Freedom of Information Act?

Page 5, Article 6.2 states: "...the Laboratory in reporting the results of cooperative research may publish Subject Data, subject to the provisions of paragraph 6.3 below, and provided the Council is given 45 days to review the manuscript and provide suggestions before publication". While the Council does not have the right to suppress publication of the research, this clause certainly gives the Council an opportunity to influence the interpretation of the research prior to its public release. Does this requirement for Council review apply to all results of the study or is it restricted to the results on phthalates, brominated flame retardants, and perfluorinated compounds?

Page 4 of the Statement of Work for this CRADA indicates that EPA has formed a Peer Advisory Committee. If the Council is participating as a partner in the study, the Council can already supply technical expertise from the industry to EPA. In fact, EPA scientists would be free to discuss technical matters with Council scientists even outside of a formal cooperative agreement. The additional committee seems superfluous under these circumstances seeing that half its membership will be comprised of scientists from ACC member companies. For objective substantive expertise, the Agency should form a federal advisory committee of technical experts conforming to the requirements of the Federal Advisory Committee Act with a membership independent of both the Council and the EPA office performing the study. The establishment of a non-FACA committee suggests the public will not have access to the agenda, work products, or deliberations of this Committee. The establishment and membership of the Committee also suggests a role for the Council above simple provision of funds for this study.

The language of the CRADA, as discussed above, indicates the Council is much more than a silent partner who has simply provided financial resources to this research study. Dr. Bahadori's role as a Project Manager, the requirement for Council pre-review of study results, and the Council's role on the Committee indicate, contrary to Dr. Gilman's statement in the Post article, that indeed strings are attached to these funds. The Council is being compensated for their two million dollars with access and influence into the research goals, conduct and results of this study.

Additionally, we are concerned with issues that are not addressed in the CRADA, that pertain to the agreements the federal agencies have made with the study participants on the handling of the personal and private medical information to be gathered over the course of this study.

Human research subjects are being recruited to participate in this study and will provide data of a personal and private nature. Question 10 on the question-and-answer sheet found on the Children's Environmental Exposure Research Study (CHEERS) website (copy attached) indicates that the child's name, family members' names, and the information gathered from this study will be kept confidential and that all project staff signed an Assurance of Confidentiality. Please provide us with a copy of this form and a list of all project staff who have signed the form. Will the confidential information gathered on the participants in this study be shared with any employees or representatives of the Council? Will the members of the Advisory Committee have access to this confidential information?

Federal agencies and their employees are bound by statutes such as the Privacy Act to abide by confidentiality agreements entered into with research subjects. However, Council employees are not. The CRADA ensures EPA must continue to abide by all statutes requiring them to maintain confidential business information and trade secrets. However, the CRADA is silent on the obligations, if any, of the Council's personnel to maintain the confidentiality of information gathered on human subjects in this study. Even if the Council's confidentiality requirements were specified in the CRADA, the assertion that the Council would not share confidential information about these participants outside the Council membership essentially provides no assurance of confidentiality. If Dr. Bahadori and the other Council scientists were to sign an Assurance of Confidentiality would they violate the agreement by sharing the information with Council staff who did not sign the agreement or with a representative of one of the Council's member companies? Please provide us with copies of any confidentiality agreements signed by employees of the Council.

The materials on EPA's website describing the study, its purpose, and the participating agencies do not include any information about the Council other than to acknowledge the Council as a partner. It appears that participants will be recruited into this study in the belief they are part of a government-managed, government-funded study. If the information provided to prospective participants includes nothing about the Council other than the Council's name listed as a partner, this is insufficient. For informed consent, all participants in this study should be made aware that ACC is a chemical industry trade association that

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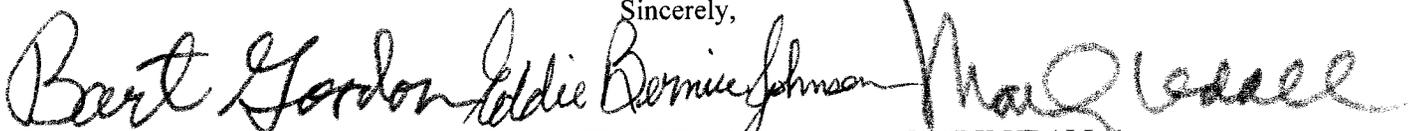
lobbies and conducts research on behalf of its member companies. Participants should be informed whether Council personnel will have access to the participants' confidential information and if the industry will have access to this information. Thus, we ask that you also provide to us with the following materials:

- 1) copies of all information supplied to potential participants and used to recruit participants to this study
- 2) copies of all consent agreements that participants were asked to sign during the recruitment process
- 3) copies of all agreements signed by the federal and state partners and supplied to the participants regarding the obligations of the research partners to maintain the confidentiality of information gathered on the participants during the course of the study.

Please provide us with responses to the questions we have raised and all requested materials by December 15, 2004. In addition to the concerns raised by this CRADA, we have ethical concerns about the design and execution of this study that we will raise in another letter.

It is unfortunate the Agency did not consider the perception problems associated with the establishment of this agreement. If the addition of analyses of phthalates, brominated flame retardants, and perfluorinated compounds was important to the Agency, additional funds should have been found by reallocating them from other areas. The Agency's credibility is worth more than \$2.5 million dollars.

Sincerely,



BART GORDON
Ranking Member
Committee on Science

EDDIE BERNICE JOHNSON
Ranking Member, Subcommittee
on Basic Research

MARK UDALL
Ranking Member, Subcommittee
Environment, Technology and
and Standards

Attachment

**Longitudinal Study of Young Children's Exposures in their Homes to Selected Pesticides,
Phthalates, Brominated Flame Retardants, and Perfluorinated Chemicals
(A Children's Environmental Exposure Research Study- CHEERS)**

Questions & Answers

Q1: What is the CHEERS study?

A: CHEERS stands for Children's Environmental Exposure Research Study. The purpose of this study is to learn about young children's exposures to pesticides and chemicals present in common consumer products used in their homes.

Q2: Why is this important?

A: Currently, the data on very young children's exposures to pesticides and chemicals in consumer products at home are very limited and not adequate for scientists to fully understand this issue. CHEERS is designed to provide more information to help scientists understand how young children are exposed to pesticides and other chemicals, when the exposures occur, and how much chemical they are exposed to at home. Your participation will contribute to the success of this important study. The results will benefit young children in the future.

Q3: Who is in charge of this study?

A: The U.S. Environmental Protection Agency is the primary sponsoring agency. Florida's Duval County Health Department, the Centers for Disease Control and Prevention (CDC), and the American Chemistry Council are partners with EPA on this study.

Q4: Why must I live in Duval County? (Why is this study taking place in Duval County?)

A: CHEERS is being conducted in Duval County because of the warm weather and year-round pesticide (bug sprays) use in the area. For logistical reason, we need to have all participants in this area so our staff won't have to travel a long distance to conduct study activities.

Q5: Who are the researchers?

A: The EPA Principal Investigators are Drs. Nicolle Tulse and Roy Fortmann. The Co-Principal Investigators are Drs. Suzanne McMaster (EPA), Lisa Melnyk (EPA), and Dana Barr (CDC). Here is Dr. Tulse's contact information:

Dr. Nicolle Tulse
U.S. Environmental Protection Agency (E205-04)
4930 Old Page Road
Research Triangle Park, NC 27709
Tel: 919-541-1077
Email: Tulse.Nicolle@epa.gov

Q6: Why does my child have to be a newborn or approximately 12 months old?

A: Currently, the data on very young children's exposures are very limited. Children at these ages have a lot of developmental changes that may affect their exposure to pesticides. Although there have been a number of exposure studies performed for older children, there have been few studies for this age group

Q7: Do I have to use a certain amount of pesticides or use pesticides a certain number of times?

A: No, you are not required to change any of your regular household routines or how you normally use bug sprays (pesticides). However, we do need your help to tell us when you plan to use bug sprays or when someone else is going to spray your home so we can arrange a time to do the study activities before and after the use of bug sprays (pesticides).

Q8: What if I want to discontinue my participation? Can I stop at any time?

A: Yes. Participation is voluntary and you may stop your participation at any time. Every participant is very important to the study and it is very difficult to replace someone who decides not to continue to participate. Our study director will be very happy to talk with you if you have any concerns or questions. The entire research team will try their best to make your participation an interesting and rewarding experience.

Q9: Is there any risk to my family?

A: No. You and your child will not experience any risks from participating in this study. You are not required to change any of your regular household routines. Your participation does not mean that dangerous levels of chemicals are present in your area.

Q10: Are the results confidential?

A: Yes. Your child's name, the names of your family members, and the information gathered from this study will be kept confidential. All project staff members have been trained on the subject of confidentiality and have signed an Assurance of Confidentiality. All study-related computer data files are password-protected. All hard-copy (paper) contact and identification information is stored in a locked file cabinet. Only authorized research staff has access to the study information. Once the study is completed, the identifying information will be destroyed. To help insure your privacy, we will also obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services. With this certificate, the researchers cannot be forced to tell people, including courts, about your study information without your written permission.

Q11: Will my family receive the results of the study?

A: Yes. You will receive a project progress report on a regular basis during the two-year study period. A final study summary report will be sent to all participants when it becomes available.

Q12: Whom can I contact for more information?

A: If you have any questions or want more information on the study, please call our toll-free number and Cherry Jackson will answer your questions. The number is 1-877-810-9530, ext. 503. Also, you may visit our website: <http://www.epa.gov/cheers/>.