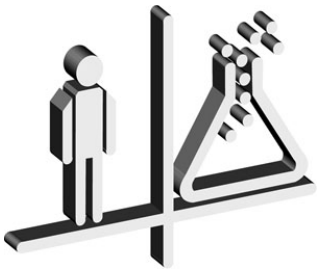

American Council on Science and Health

December 12, 2005

The Honorable Steven Johnson
Administrator
U.S. Environmental Protection Agency
Mail Code: 7502C
1200 Pennsylvania Ave., NW
Washington, DC, 20460-0001

RE: Proposed Guidelines on the use of human volunteers in pesticide safety studies; Docket ID Number OPP-2003-0132

The use of human volunteers in research studies has proven critical in the advancement of scientific and medical progress. It is well known that such research has contributed to the development of new medical techniques, medical devices, and drugs that mitigate and cure a spectrum of diseases. Less recognized is the value such research could bring to pesticide safety policy at the Environmental Protection Agency (EPA).

The use of human volunteers in pesticide safety studies is vitally important for a number of reasons. It will give the agency a powerful tool for ensuring that pesticide products are as safe as possible. In addition, it is necessary to increase the availability of valuable public health products such as those designed to control insect-borne diseases like West Nile virus and Lyme disease, disinfect our hospitals and our homes, and produce a safe and plentiful food supply.

EPA's guidelines promise to set a precedent that could exert an impact on long-term research goals and practices at various government agencies. Accordingly, EPA guidelines should focus on facilitating such research while assuring that it is done ethically.

In 2000, EPA's Science Advisory Board and its Science Advisory Panel jointly concluded that human testing in pesticide safety trials can be justified on ethical and scientific grounds as long as it is conducted under appropriate guidelines. In 2004, The National Academy of Sciences (NAS) released a report on the topic, finding that ethically conducted human studies can improve "the accuracy of the science employed in regulatory decisions …" and that such studies can provide "a societal benefit that can justify the conduct of a human dosing study."

The NAS recommended that EPA establish a process to set standards for such research. Such standards should ensure minimal risk to all study volunteers, and they should ensure that volunteers provide truly informed consent. The academy noted that with the application of such standards, human dosing studies should "pose no identifiable risk" to study participants and

provide “a reasonable certainty” for “no harm.”

We support the EPA’s development of such guidelines and urge the agency to ensure the integrity of the scientific process, rather than reacting to political pressures that attempt to undermine such useful research.

Sincerely,

Elizabeth Whelan, Sc.D., M.P.H., President, American Council on Science and Health
Gilbert Ross, M.D., Medical/Executive Director, American Council on Science and Health
Henry I. Miller, M.S., M.D., Research Fellow, Hoover Institution
Fred Smith, President, Competitive Enterprise Institute
Richard J. Pollack, Ph.D., Harvard School of Public Health
Donald A. Henderson, M.D., M.P.H., Johns Hopkins Bloomberg School of Public Health
Joseph F. Borzelleca, Ph.D., Professor Emeritus, Department of Pharmacology and Toxicology, Virginia Commonwealth University
J. Donald Millar, M.D., D.T.P.H. (Lond.)
Wallace I. Sampson, M.D., Stanford University School of Medicine
F. Peter Guengerich, Ph.D. Vanderbilt University School of Medicine
James T. Stevens, Ph.D., Professor of Physiology and Pharmacology, Wake Forest University School of Medicine
Roger O. McClellan, DVM, MMS, DSc(Honorary), Dipl-ABT, Dipl-ABVT, Fellow-ATS Advisor, Toxicology and Human Health Risk Analysis
Manfred Kroger, Ph.D., Professor of Food Science Emeritus, Pennsylvania State University
Steven Milloy, MHS, JD, LLM, Free Enterprise Action Fund
Dean O. Cliver, Ph.D., School of Veterinary Medicine, University of Calif.-Davis.
Bernard L. Cohen, D.Sc. University of Pittsburgh
Dr. Curtis D. Klaassen, Univ. of Kansas Medical Center Department of Pharmacology, Toxicology, & Therapeutics
Hugh E. Wise, Ph.D. U.S. Environmental Protection Agency, Office of Water (retired)
George E. Ehrlich, M.D., F.A.C.P., M.A.C.R., FRCP (Edin) Philadelphia, PA
Donald G. Cochran, Ph.D.
James C. Lamb, IV, J.D., Ph.D., DABT, The Weinberg Group
Randall G. Knepper, President, Michigan Mosquito Control Association
Edgar J. Schoen, M.D. Kaiser Permanente Medical Center
Richard W. Merritt, Professor and Chair, Dept. of Entomology, Michigan State University
Janet Weiss, M.D.
Dennis Avery, Center for Global Food Policy, Hudson Institute
Alex Avery, Center for Global Food Policy, Hudson Institute
Alan G. McHughen, D.Phil. University of California, Riverside
Chris F. Wilkinson, Ph.D., Wilmington, NC
William W. Greaves, M.D., MSPH, Medical College of Wisconsin
James E. Oldfield, Ph.D., Oregon State University
Thomas R. DeGregori, Ph.D., Professor of Economics, University of Houston
Angela Logomasini, Director of Risk and Environmental Policy, Competitive Enterprise Institute