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Public Information and Records Integrity Branch (PIRIB)
7502C
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, DC 20460-0001

RE: Docket ID number OPP-2003-0132

We, the undersigned organizations dedicated to promoting and protecting human health and safety, are pleased to have the opportunity to comment on potential U.S. Environmental Protection Agency (EPA) criteria and standards relating to research involving human subjects.

This issue is of the highest import. Protection of human subjects and support of ethically and scientifically conducted studies should be an Agency-wide goal and standard.

Over the years, many organizations representing pediatrics, health, the faith community and other public interests have urged the Agency to assure protections for human test subjects, especially those who were being intentionally dosed with pesticides with the purpose of eliminating or lessening regulatory safety margins. It is distressing that the EPA is in the situation where on one hand it has no policies or oversight system to protect human subjects in tests (theoretically discouraging such tests on humans), while on the other hand accepting such experimental studies when submitted in the course of pesticide regulation. We commend the Agency for proceeding with rulemaking on this topic and urge expeditious action.

Principles

Our organizations urge the Agency to follow these principles in setting these guidelines and standards:

Any policy adopted by the Agency should reflect the highest standards of respect for human subjects and should prohibit research protocols that override the interests of subjects in order to obtain useful data.

Any policy adopted by the Agency must reflect a special concern for the interests of vulnerable populations, such as fetuses, children, adolescents, pregnant women, the elderly, and those with fragile health due to compromised respiratory function or other reasons.

In no case should developing humans (i.e., the fetus, infant, young children, or adolescents) be exposed to toxic chemicals. There are currently too many unknown dangers to justify such studies, even under the most extraordinary circumstances.

Children should not be subjects of studies involving intentional dosing.

The Agency's criteria and standards must consider the implications of all studies for a variety of different populations, from all children, to children with disabilities, to children in minority and/or farmworker communities, to farmworkers and others. If the EPA does not assure adequate protection from exposure to toxicants in the environment, there are groups that will be

more affected; most often these are low income or minority communities. These same communities are also the ones that most likely would be tempted by large incentives to participate in human studies that are of no benefit to them personally or to their communities. This critical issue must be addressed.

The EPA should take whatever administrative action is necessary to extend the protections of the Common Rule (40 CFR Part 26) to all human research activities whose results will be submitted to the Agency.

Bad science is always unethical. Research protocols that are fundamentally flawed, such as those with sample sizes inadequate to support reasonable inferences about the matter in question, are unjustifiable.

Studies that involve dosing people orally with organophosphate pesticides to determine acute "no effect" levels (the human oral pesticide toxicity studies that were the genesis of this controversy) are not ethical in that they serve no purpose in improving our ability to diagnose, treat, or understand the etiology of disease nor do they provide information sufficient to overcome the risks to individual subjects, and thus the EPA should not allow or accept such third-party studies. Additionally, conducting such human oral pesticide toxicity studies in adult volunteers provides limited or no information that protects children. The Agency must not assume that such tests are going to prove protective of children.

If it can be justified at all to expose human subjects intentionally to toxic substances, the threshold of justification for such action should be very high. Pesticide exposure to human subjects must be approached with the greatest degree of caution. If studies are to be accepted by the Agency, the Agency has the obligation to assure that the studies have been conducted with the very highest of scientific and ethical standards.

In considering research protocols, it is not enough to determine a risk/benefit ratio; it is important also to consider the distribution of risks and of benefits, and to ensure that risks are not imposed on one population for the sake of benefits to be enjoyed by another. It is also important to be sensitive to the difference between a reversible risk and one that may be irreversible, such as possible interference with normal neurological development.

Implementation

In implementing these principles:

The Agency must adopt strong and enforceable standards with regards to all regulatory data submissions for human testing of pesticides and other chemicals, based on the principles listed above. Food and Drug Administration (FDA) policy provides a number of safeguards and the Agency should follow FDA's lead and promulgate enforceable regulations for third parties that clearly articulate policies and expectations. However, the FDA standards should be viewed as a starting point. Clearly, we should have even stronger standards for pesticides and industrial chemicals than for drugs and medical devices.

The Agency must delegate the responsibility for this task to one strong central authority, such as the Office of General Counsel, and provide adequate resources and training for this effort. This includes cleaning its house with regards to its own internally conducted and funded research to train its scientists and to assure that the highest ethical standards are followed there as well.

The Agency must move forward promptly.

Thank you for your consideration of these vital issues. For more information please contact Daniel Swartz, Executive Director of the Children's Environmental Health Network at 202-543-4033, extension 16.

Sincerely,

Children's Environmental Health Network
Action Now
Alliance for Healthy Homes
American Public Health Association
Association of Occupational and Environmental Clinics
Association of Women's Health, Obstetric and Neonatal Nurses
Beyond Pesticides
Canadian Environmental Law Association
Center for International Environmental Law (CIEL)
CHEC
Coalition for Environmentally Safe Schools
Coalition on the Environment and Jewish Life
Consumers Union
DES Action USA
Environmental Defense
Environmental Health Strategy Center
Farmworker Justice Fund Inc.
Generation Green
Healthy Schools Network, Inc.
Institute for Children's Environmental Health
Learning Disabilities Assn. of America
Learning Disabilities Association of Canada/Troubles d'apprentissage - Association canadienne
Lutheran Office for Governmental Affairs
Mercury Policy Project
Michigan Environmental Council
Minnesota Children's Health Environmental Coalition
Mount Sinai Center for Children's Health and the Environment
National Association of School Nurses
National Black Environmental Justice Network
National Catholic Rural Life Conference
National Environmental Trust
National Organization of Nurse Practitioner Faculties
Northwest Coalition for Alternatives to Pesticides
Our Bodies Ourselves
Pesticide Action Network North America
Pesticide Education Center
Presbyterian Church (U.S.A.) Washington Office
Science and Environmental Health Network
Trust for America's Health
United Church of Christ Network for Environmental and Economic Responsibility
United Methodist Church General Board of Church and Society
West Harlem Environmental Action

