

December 10, 2001

Honourable Alan Rock
Minister of Health
Tunney's Pasture, Brooke Claxton Building
Ottawa, Ontario
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VIA FAX (613) 952-1154

RE: USEPA Decision to Accept Industry Testing of Pesticide Toxicity in Human Subjects

The Pest Management Regulatory Agency (PMRA) has recently stated that it will closely follow the practices of the United States Environmental Protection Agency (USEPA) in its re-evaluation of pesticides. We write today concerning the recent policy reversal in the United States that we believe needs to be directly addressed, and opposed by the government of Canada. We are deeply concerned that the USEPA is reversing its policy on the acceptance of industry test data derived from the experimental dosing of human subjects with pesticides. This practice has been appropriately greeted with grave concern by the medical, scientific, public interest, religious, environmental, consumer and health communities in recent years. We wish to express our opposition to this practice on moral, ethical and scientific grounds.

In May of 2000, the Canadian Environmental Law Association and the Ontario College of Family Physicians Environmental Health Committee published a detailed study on children's environmental health. The analysis of regulatory practices regarding pesticides and other toxic substances in that report included a detailed review of the implementation of the *Food Quality Protection Act* in the United States. Excerpted from the CELA-OCFP report and attached to this letter is a review of the controversy surrounding the practice of testing pesticides on humans. The report recommended that the PMRA, as part of a government-wide approach, immediately implement a policy of refusing to accept from pesticide companies new or existing toxicity data derived from experiments on human "volunteers."

The Clinton Administration opposed the practice of human testing on the recommendation of a detailed investigation by the Science Advisory Board. That investigation brought to light the scientifically dubious and ethically indefensible rationale and implementation of this practice. The pesticide industry argues that such testing is no different than toxicity testing of new drugs. However, bioethicists disagree. Pesticides are not therapeutic agents. In the case of drugs, clinical trials are intended to determine the health benefits of the drugs being tested. In contrast, the objective of testing pesticides in humans is to avoid the application of a regulatory safety margin. By dosing humans directly, the industry wants to avoid the ten-fold uncertainty factor that is applied to the results of animal studies to account for variability between animals and humans. These tests are not only unethical but also provide a false sense of security.

Because the effects of toxicants in children are not only quantitatively, but also qualitatively different from effects in adults, data obtained from testing of adults are useless for extrapolation to the health endpoints that are of primary concern with pesticides - developmental effects in children. A bitter irony in this debate is that the renewed practice of testing human subjects has arisen to avoid the application of safety margins by a law that was passed to provide greater protection to children.

The ethical conduct of investigators is compromised when they stand to benefit financially from their research results. Such investigators are perilously close to violating their position as a “responsible investigator” as expressed in the Common Rule. The Common Rule is the most recent international expression of policy for the protection of human subjects, the first such expression having arisen in the Nuremberg Code.

The second key component of the Common Rule is the notion of informed consent. Informed consent can only occur between two adults. The human “volunteers” in these pesticide tests have in some cases been company employees, and in some cases the “volunteers” are apparently paid several hundred dollars to participate. It is of grave concern if the alleviation of poverty motivates their participation.

We urge you to confirm the Canadian government’s current position that it will not accept new or existing toxicity test data derived from experiments on humans. We also urge you to reject the USEPA reversal on this policy. Please respond at your earliest convenience to clarify the Canadian position on this matter.

Yours truly,

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