December 9, 2004

The Honorable Michael Leavitt
Administrator
U.S. Environmental Protection Agency
Ariel Rios Bldg. (1101A)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Leavitt:

We write you today to urge that the U.S. Environmental Protection Agency (EPA) continue to support and advance the testing of chemicals for their potential to injure the young, developing brain. We cannot afford to ignore the developing brain in safety evaluations for chemicals.

As you know, the EPA established a validated guideline for testing developmental neurotoxicity (DNT) in animals in 1991, although such testing has never been required before putting new industrial chemicals or pesticides on the market – even where these compounds are known neurotoxins. As we have stated in letters to the Agency previously,[1,2] we strongly urge the EPA to implement the recommendation of its scientific staff and external scientific advisors to make DNT testing a core requirement for registering pesticides by submitting the proposed revisions to 40 CFR Part 158 to the Office of Management and Budget for promulgation. This requirement will promote better, science-based regulation of these compounds.

Testing for developmental neurotoxicity is critical because increasing numbers of our children are being diagnosed with learning and other developmental disabilities, and no one can account for the rise. Nearly 12 million American children (17%) now suffer from one or more learning, developmental or behavioral disabilities. The overall costs to families, and the economic costs to society, are immense. At the same time, only a fraction of potential neurotoxins under regulation have been tested for their possible impacts on child brain development. At least one-quarter of hazardous industrial chemicals for which occupational exposure limits have been set have demonstrated neurotoxic effects.[3] Also, of nearly 1,200 suspected neurotoxic industrial chemicals, only a handful have been assessed for their potential to affect brain development to date.[4]

---

1 February 28, 2004: Re: Finalizations of Revisions to CFR 158: Toxicity Testing Requirements to include developmental neurotoxicity testing. Signatories: Learning Disabilities Association of America (LDA), Children's Environmental Health Network, Environmental Defense, Natural Resources Defense Council (NRDC), National Medical Association.

2 May 12, 1999: Re: Developmental Neurotoxicity Data gaps and the children's 10X Safety Factor. LDA, Consumers Union, NRDC, Science and Environmental Health Network, Physicians for Social Responsibility, U.S. Public Interest Group

3 Anger WK. Neurobehavioral testing of chemicals: impact on recommended standards. *Neurobehavioral Toxicology and Teratology*. 1984; 6:147-153.

4 Stein J, et al. In harm's way: toxic threats to child development. *Journal of Developmental and Behavioral Pediatrics.* 2002; 23:S13–S22.

Public health science can now point to several examples where, as science progressed, levels of human exposure to chemical neurotoxins once thought to be safe have proved to be levels capable of inducing brain injury and harm to children. Lead and PCBs are the most prominent such examples. The adverse economic impact (in terms of lost productivity) on the American economy from lead-induced injuries in children alone likely amounts to tens or hundreds of billions of dollars annually[5]. An investment in such safety evaluations for pesticides (and chemicals in general) would constitute not only an investment in healthy children, but an investment in America's economic future competitiveness.

Given this history, we support chemical registrants continuing to pursue testing laboratory animals according to the EPA's two "developmental neurotoxicity" (DNT) guidelines: 40 C.F.R. 799.9630 under TSCA and OPPTS 870.6300 under FIFRA. These test measures have been standardized and validated in two large interlaboratory studies. In 1985 a major US study was conducted to check the comparability of a number of behavioral tests across six different laboratories which led to these validated and standardized test batteries[6]. Again in Europe, five laboratories in four countries collaborated in the evaluation of the detection levels of different test methods[7]. Both showed comparable sensitivities for the behavioral test batteries, automated test systems and the neurochemical assays. Such testing has been found to be important to uncovering previously unrecognized hazards to brain development, resulting in necessary regulatory action on common household pesticides, e.g. chlorpyrifos and diazinon.

We further urge EPA to proceed as quickly as possible to capture the science embodied in the 56 developmental neurotoxicity (DNT) studies already submitted to it under the 1999 Data Call-In (DCI) by expediting the formal internal scientific reviews of those studies and making the results (as well as data, when appropriate) available to the public. Nineteen of these studies are for organophosphate pesticides, which EPA considers the class of pesticides posing the greatest risks to children. We would note that the public has already waited five years for the completion and review of such studies. Also, EPA scientists have indicated to us that these developmental neurotoxicity studies have proved to be 4- to 5-fold less expensive than the industry predicted when the DCI was issued.

Finally, we would caution against calls advocating for EPA to simply turn its back on scientific test data and instead to focus exclusively on adding extra "safety factors" into its risk assessments. We strongly urge that what is needed is better, more extensive, scientific evaluation of chemicals, *combined with* presumptive use of additional safety factors sufficient to assure that children will not be harmed from chemical exposures until the overwhelming ignorance about the nature of chemical toxicity and exposure has been addressed. Such is the approach clearly envisioned by Congress when it passed the Food Quality Protection Act (FQPA) of 1996. And yet, even where the FQPA suggests an additional children's margin of safety should be presumptive in EPA's pesticide risk assessments where exposure and/or toxicity studies are lacking, the Agency has not used this safety factor when DNT studies were lacking. For example, the EPA failed to use an additional children's 10-fold safety factor in its evaluations for many if not most of the organophosphate insecticides, despite the then-absence of DNT studies for these neurotoxins. In fact, the public has been inappropriately tasked with justifying the use of safety factors rather than placing the burden on the industry to demonstrate safety through comprehensive testing and show safety factors are not needed.

---

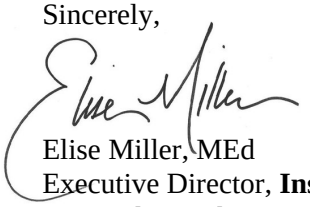
5 Grosse S, et al. Economic gains resulting from the reduction in children's exposure to lead in the United States. *Environmental Health Perspectives.* 2002; 110:563–569.

6 Elsner J, Hodel B, Suter KE, et al. Detection limits of different approaches in behavioral teratology study, with correlation of effects with neurochemical parameters. *Neurotoxicology and Teratology*. 1988; 10: 155-167.

7 Buelke-Sam J, Kimmel CA, Adams J, Nelson CJ, Vorhees CV, Wright DC, St Omer V, Korol BA, Butcher RE, Geyer MA, et al. Collaborative Behavioral Teratology Study: results. *Neurobehavioral Toxicology and Teratology*. 1985 Nov-Dec; 7(6):591-624.

We thank you for your consideration of this letter, and for the Agency's continued support for toxicity testing of pesticides for their potential impacts on children in advance of registration. We will contact your office again to follow up on the recommendations in this letter.

Sincerely,



Elise Miller, MEd
Executive Director, **Institute for Children's Environmental Health**
National Coordinator, Learning and Developmental Disabilities Initiative

Additional signatories (all members of the Learning and Developmental Disabilities Initiative):

American Association on Mental Retardation
- Doreen Croser, Executive Director

Clean Water Action – California
Lena Brook, Interim Director

Healthy Children Organizing Project
- Neil Gendel, Director

Healthy Schools Network, Inc.
- Claire Barnett, Executive Director

Institute for Agriculture and Trade Policy- David Wallinga, MD, Senior Staff Scientist

Learning Disabilities Association of America
- Suzanne Fornaro, President

Learning Disabilities Association of California and Marin Golden Gate Learning Disabilities Association
- Jo Rupert Behm, MS, RN, LDA-CA Healthy Children Project Coordinator

Mercury Poisoning Project
- Arnold Wendroff, PhD, Director

Oregon Toxics Alliance
- Lisa Arkin, Executive Director

Science and Environmental Health Network
- Ted Schettler, MD, MPH, Science Director

The Arc of the United States
- Steven M. Eidelman, Executive Director

United Cerebral Palsy Research and Educational Foundation
- Liz Savage, Director, Health and Housing Policy