



Physicians for Social Responsibility

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Dr. Michael D. Shelby,  
CERHR Director  
NIEHS  
PO Box 12233, MD EC-32  
Research Triangle Park, NC 27709

September 23, 2005

Re: Request for comments per Federal Register Vol. 70, No. 145, Friday July 29, 2005

Dear Dr. Shelby:

On behalf of San Francisco Bay Area Physicians for Social Responsibility (SF PSR), we write today regarding the NTP-CERHR's Expert Panel Update on the Reproductive and Developmental Toxicity of Di(2-ethylhexyl) Phthalate.

Since the NTP's first report on DEHP, regulators in California have thoroughly reviewed the reproductive and developmental toxicity of DEHP and subsequently determined that under the Safe Drinking Water and Toxic Enforcement Act of 1986, DEHP is a developmental and male reproductive toxicant. In their scientific review, they had the opportunity to review a number of the documents that have been submitted to the current NTP-CERHR record.

We have included a report from California's Office of Environmental Health Hazard Assessment (OEHHA) regarding the proposed maximum allowable daily limits of oral DEHP exposure, which summarizes OEHHA conclusions on the science of DEHP. We would respectfully request that the OEHHA report, along with this letter, be entered into the official record of the expert panel and be considered as they review the data associated with DEHP.

In particular, scientists from OEHHA looking at the raw data from Mitsubishi made several important points. OEHHA's staff reviewed relevant science regarding the male reproductive system of common marmosets and concluded that, "the testis of the common marmoset indeed has some unique characteristics that are dramatically different from other mammals including rats, cynomolgus macaques, and humans" (page 9, Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Di(2-ethylhexyl)phthalate (DEHP) by Oral Exposure, June 2005, OEHHA, Reproductive and Cancer Hazard Assessment Section). In addition, OEHHA's scientific staff pointed out that:

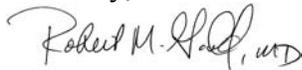
vitamins C and E are protective against the testicular effects of DEHP in rats or mice (Ishihara et al., 2000; Ablake et al., 2004). Common marmosets require high levels of dietary vitamin C so regular diets for this species usually contain high levels of vitamin C supplements (e.g., MCSI, 2003). Serum levels of vitamin C in common marmosets are

markedly higher (2.56 mg/100ml in average) than most other mammals (0.63 mg/100 ml in average in humans; Flurer and Zucker, 1987; 1989; Hampl et al., 2004), creating the possibility of reduced sensitivity to DEHP in this species. Based on the facts discussed above, OEHHA has determined that the data from studies in common marmosets should not be used as the basis for MADL development for DEHP. (OEHHA, page 9.)

These important points should be considered and the panel should thoroughly review the marmoset and Schilling studies, since they have not undergone peer review and been published.

Thank you.

Sincerely,

A handwritten signature in black ink that reads "Robert M. Gould, MD". The signature is written in a cursive style with a large, stylized initial 'R'.

Robert M. Gould, MD  
President

Julie Silas, JD  
Program Director