May 27, 2010

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Comments of the Patient, Consumer, and Public Health Coalition
on
Proposed rule (reopening of comment period) on bottled water and the deferred final action on the proposed allowable level for the chemical di (2-ethylhexyl) phthalate (DEHP)

[Docket No. FDA-1993-N-0259]

The Patient, Consumer, and Public Health Coalition—which includes nonprofit organizations that represent patients, consumers, scientists, and researchers—supports the FDA's proposed rule for an allowable level of 0.006 milligrams/liter (6 parts of DEHP per billion parts of water (6 ppb)) for di (2-ethylhexyl) phthalate DEHP.

In animals, DEHP is a carcinogen, reproductive toxicant, and developmental toxicant.[1] Scientific evidence suggests that phthalates may be harmful to humans, and increase the risk of serious diseases such as cancer and reproductive problems. That is why the U.S. Department of Health and Human Services "has determined that DEHP may reasonably be anticipated to be a human carcinogen."[2]

Research indicates that boys exposed to phthalates such as DEHP may be more likely to develop smaller genitals and incomplete descent of the testicles.[3] Boys who are born with undescended testicles are at higher risk of testicular cancer, a disease that primarily affects teenagers and young men. Studies by Harvard researchers have shown phthalates such as DEHP may alter human sperm DNA and semen quality.[4, 5, 6, 7] Based on these and other concerns, the Consumer Product Safety Improvement Act of 2008 banned the use of DEHP in children's toys and products.

The implementation of this proposed rule has been deferred since 1993 on the grounds that the standard conflicted with an existing prior sanction for food and liquid packaging contact materials. Since that time, based on information from industry, it appears that DEHP is "not being used in caps or closures for bottled water in the U.S."[8] Also, the European Commission has stopped the use of DEHP in plastic caps, lids or metal caps, and the International Bottled Water Association has accepted the 6 ppb standard.

The FDA's proposed rule of 6 ppb of DEHP in bottled water conforms with current industry standards, but it is crucial that this proposed rule become the regulatory standard because otherwise industry standards could change in the future, or some companies could ignore them. If the 6 ppb standard is finalized, the FDA states that "bottled water products with DEHP levels above the finalized level will be misbranded if the products do not bear label statements of substandard quality."[8] This gives the FDA the power to enforce the 6 ppb standard, and will ensure that the public—especially children whose developing brains and bodies are more vulnerable to DEHP than adults—are protected from the adverse health effects of DEHP-tainted bottled water.

Because "the EPA has determined that DEHP is a probable human carcinogen,"[2] we strongly support this proposed rule, which will ensure that neither adults nor children will be exposed to DEHP in their bottled drinking water.

Breast Cancer Action
Community Access National Network (CANN)
Consumer Federation of America
Consumers Union
National Consumers League
National Physicians Alliance
National Research Center for Women & Families/Cancer Prevention and Treatment Fund
National Women's Health Network
Our Bodies Ourselves
U.S. Public Interest Research Group (U.S. PIRG)
WoodyMatters

For additional information, contact Paul Brown, Government Relations Manager for the National Research Center for Women & Families/Cancer Prevention and Treatment Fund at 202-223-4000 or pb@center4research.org

[1] Shea, KM, (2003). Pediatric Exposure and Potential Toxicity of Phthalate Plasticizers, *American Academy of Pediatrics*, Vol. 111 No. 6.

[2] Agency for Toxic Substances and Disease Registry (ASTSDR) (2002). Toxicological Profile for di (2-ethylhexyl) phthalate. Update. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

[3] Swan S., Main, K.M. *et al* (2005). Decrease in Anogenital Distance Among Male Infants with Prenatal Phthalate Exposure. *Environmental Health Perspectives 113: 1056-1061*.

[4] Duty, S. M., M. J. Silva, *et al.,* (2003). Phthalate exposure and human semen parameters. *Epidemiology* 14(3): 269-77.

[5] Duty, S. M., N. P. Singh, *et al*., (2003). The relationship between environmental exposures to phthalates and DNA damage in human sperm using the neutral comet assay. *Environ Health Perspect* 111(9): 1164-9.

[6] Duty, S. M., A. M. Calafat, *et al*., (2004). The relationship between environmental exposure to phthalates and computer-aided sperm analysis motion parameters. *JAndrol* 25(2): 293-302.

[7] Duty, S. M., A. M. Calafat, *et al*., (2005). Phthalate exposure and reproductive hormones in adult men. *Hum Reprod* 20(3): 604-10.

[8] Federal Register (2010, April 1). Beverages: Bottled Water; Reopening of the Comment Period. Docket No. FDA 1993-N-0259.