Resolution 05-04

Encouraging Alternatives to PVC/DEHP Products in Health Care

WHEREAS Di-ethylhexyl phthalate (DEHP) is a phthalate used as a plasticizer in polyvinylchloride (PVC) medical devices, including IV bags, IV tubing, enteral feeding sets and urinary catheters[i]; and

WHEREAS DEHP is not covalently bound to the plastic matrix and has been found to leach from PVC medical devices into blood, blood products, lipophilic substances and medical solutions[ii], [iii], [iv] ; and

WHEREAS neonates may receive high exposures to DEHP and its toxic metabolites, including monoethylhexyl phthalate (MEHP), when undergoing replacement of blood products, exchange transfusions, receipt of Total Parental Nutrition (TPN), extracorporeal membrane oxygenation (ECMO), and other procedures[ii]; and

WHEREAS infants in neonatal intensive care units (NICUs) receiving intensive therapy with PVC medical devices were exposed to MEHP at much higher levels than the general population – 25 times higher on average and up to 50 times higher for the most exposed[v]; and

WHEREAS in-vitro, animal, and human neonate studies have shown DEHP to have an adverse effect on the tissues of the male reproductive tract, and on the lungs, kidney, and liver when administered at levels similar to those to which neonates are exposed during medical treatment in NICUs[vi] ; and

WHEREAS the US Food and Drug Administration (FDA) has issued a Public Health Notification for use of DEHP/PVC medical devices[vii]; and

WHEREAS PVC produces dioxin during manufacture and, if incinerated, upon disposal[ii]; and

WHEREAS dioxin is a known human carcinogen that is highly toxic, persistent and bioaccumulative[viii]; and

WHEREAS alternative non-PVC products and PVC products that use alternative plasticizers are commercially available for most medical devices[ix]; and

WHEREAS many health care facilities are phasing out PVC products, especially those containing DEHP, particularly in their neonatal intensive care units, including Kaiser Permanente, Evergreen Hospital Medical Center and Group Health Cooperative[x], [xi],

THEREFORE BE IT RESOLVED THAT the Washington State Public Health Association (WSPHA) strongly urges the reduction and elimination of PVC medical device products, especially those containing DEHP, and encourages the use of safe, cost-effective, alternative products where available; and

BE IT FURTHER RESOLVED THAT WSPHA strongly urges expanded manufacturer development of safe, cost-effective alternative products to PVC medical device products, especially those containing DEHP.

Signed by: Jeff Mero, WSPHA President 2004-2005

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[i] US Food and Drug Administration; Center for Devices and Radiological Health. Safety Assessment of Di-ethylhexyl phthalate (DEHP) Released from PVC Medical Devices. http://www.fda.gov/cdrh/ost/dehp-pvc.pdf

[ii] Technical Report, American Academy of Pediatrics, "Pediatric Exposure and Potential Toxicity of Phthalate Plasticizers"; Katherine M. Shea, MD, MPH and Committee on Environmental Health; PEDIATRICS Vol. 111 No. 6 June 2003, pp. 1467-1474. http://aappolicy.aappublications.org/cgi/content/full/pediatrics;111/6/1467

[iii] Loff, S, et al. Polyvinylchloride Infusion Lines Expose Infants to Large Amounts of Toxic Plasticizers. Journal of Pediatric Surgery. 35: 1775-1781 (2000)

[iv] Kevy, S, and Jacobson, M. Hepatic effects of a phthalate ester plasticizer leached from polyvinyl chloride blood bags following transfusion. Environmental Health Perspectives. 45:57-64 (1982).

[v] "Use of Di(2-Ethylhexyl) Phthalate Containing Medical Products and Urinary Levels of Mono(2-Ethylhexyl) Phthalate in Neonatal Intensive Care Unit Infants". Ronald Green, Russ Hauser, Antonia M. Calafat, Jennifer Weuve, Ted Schettler, Steven Ringer, Kenneth Huttner, and Howard Hu . Volume 113, No. 7, July 2005 Environmental Health Perspectives*:* http://ehp.niehs.nih.gov/docs/2005/7932/abstract.html

[vi] National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR). NTP-CERHR Expert Panel Report on Di-ethylhexyl phthalate (DEHP). October, 2000. http://cerhr.niehs.nih.gov/news/index.html

[vii] US Food and Drug Administration; Public Health Notification on PVC Devices Containing the Plasticizer DEHP. July 12, 2002. http://www.fda.gov/cdrh/safety/dehp.html

[viii] Health Care Without Harm; Dioxin. http://www.noharm.org/pvcDehp/dioxin

[ix] Health Care Without Harm. Alternatives to Polyvinyl chloride (PVC) and Di-ethylhexyl phthalate (DEHP). http://www.noharm.org/details.cfm?type=document&id=591

[x] Health Care Without Harm, PVC and DEHP Resources; Case Studies; http://www.noharm.org/pvcDehp/reducingPVC#case

[xi] Press release: **New Harvard Study: Sick Infants in Hospital Intensive Care Units Exposed to High Levels of Toxic Phthalate -** Many hospitals still using DEHP-containing vinyl medical devices, despite FDA warnings; June 8, 2005.