

November 13, 2000

Jane E. Henney, MD
Commissioner
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Dear Director Henney,

The Women's Community Cancer Project (WCCP) of Cambridge, MA, urges swift action by the FDA on a citizen petition submitted by Health Care Without Harm (HCWH) which seeks labeling of DEHP-containing PVC medical devices.

In light of the recent expert panel review of phthalates by the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction, we believe there is new urgency to FDA action.

The NTP's Center expressed "serious concern" for the possibility of adverse effects on the developing reproductive tract of male infants exposed to very high levels of DEHP that might be associated with intensive medical procedures such as those used in critically ill infants. The Panel also recognized the health benefits of these procedures. The Panel expressed "concern" that exposure of pregnant women to current estimated adult exposure levels of DEHP might adversely affect the development of their offspring. The Panel also expressed "concern" that if infants and toddlers are exposed to levels of DEHP substantially higher than adults, adverse effects might occur in the developing male reproductive tract.

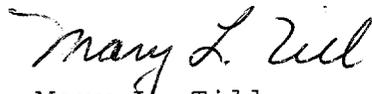
As staunch supporters of prevention over intervention after the fact, the WCCP strongly supports the Precautionary Principle which calls for precaution in the face of uncertainty. Two key elements of the Precautionary Principle are: 1) Removal of potentially unsafe products from the market until they can be proven safe, especially when safer alternatives are available and 2) informed consent. When there is danger of harm, the consuming

public should be adequately informed via labels.

In the case of DEHP-containing devices for medical uses, HCWH has identified wide availability of alternatives for many uses currently on the market. Where safer alternative are available, we urge the FDA to require the cessation of DEHP-containing device use until generally accepted evidence is gathered to either prove or disprove their safety. In cases where no reasonable alternative is known, we urge FDA to require that medical personnel inform patients of the potential hazards of these devices and why they want to use these devices in the situation at hand so that patients can give the same informed consent they are required to give when dangerous pharmaceuticals or medical procedures are recommended. It should be up to the patient to determine if the risk is worth the benefit.

We again urge prompt action on Health Care Without Harm's petition to require the labeling of all PVC medical devices that may leach phthalate plasticizers. A proactive, measured and decisive response from the FDA will, most importantly, limit DEHP exposure of pregnant women, critically ill neonates and other children and, in time, will protect the reproductive and developmental health of young Americans.

Sincerely yours,



Mary L. Till
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