

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852

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Docket No. 02D-0325

We are writing to urge the FDA to support your Public Health Notification on the plasticizer di-(2-ethylhexyl)phthalate (DEHP) in medical devices with policies that will allow providers to implement its recommendations. In particular, we urge the FDA to require labeling of medical devices containing DEHP. Our comments are offered in response to the "Draft Guidance for Industry and FDA on Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP)" recently released for comment by your agency.

The National Toxicology Program review and the FDA's own Safety Assessment have found that exposure to DEHP during early stages of development may be harmful to the developing male reproductive system. That concern was identified at levels of exposure expected to occur during some routine uses of medical devices. At-risk groups include male fetuses, neonates, and peripubertal males.

Following from these findings, the FDA, in its recent Public Health Notification, identified the following procedures as posing the highest risk of exposure to DEHP: exchange transfusions in neonates; ECMO in neonates; total parenteral nutrition (TPN) in neonates (with lipids in the bag); enteral nutrition in neonates and adults; aggregate doses in patients receiving heart transplant or undergoing coronary artery bypass graft surgery; massive infusion of blood into trauma patients; and transfusion in adults undergoing ECMO. The Public Health Notification further recommends considering alternatives to DEHP-containing devices when highest-risk procedures are to be performed on male neonates, pregnant women who are carrying male fetuses, and peripubertal males.

In its draft Guidance subsequently released to the public, the FDA identified a list of device categories regulated by its Center for Devices and Radiological Health that may contain PVC components and therefore the plasticizer DEHP. Currently, there are only a handful of devices that are labeled.

The FDA's draft Guidance recommends that manufacturers consider the feasibility of replacing PVC containing DEHP with either alternative materials or plasticizers, or using coatings that may minimize patient exposure to DEHP. If manufacturers choose not to redesign or reformulate their DEHP-containing products, the FDA recommends, but does not require, that manufacturers label their products so that users will be able to identify those products that contain DEHP.

The voluntary approach proposed by the FDA does not provide assurance that devices will be labeled, nor that practitioners will have enough information to make informed decisions. If

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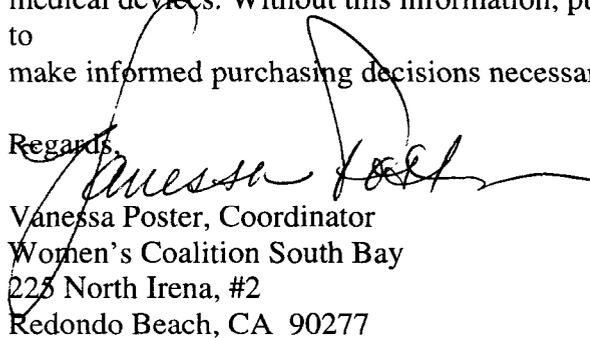
manufacturers choose not to label their DEHP-containing products, medical device users would be left in the unfortunate position of not knowing whether or not they were using a DEHP-containing product, making protection of vulnerable patients very difficult. We know from current experience as health care providers that without FDA requiring it, many manufacturers will not notify us of the presence of DEHP in medical devices. Further, obtaining information from manufacturers about whether or not a product contains DEHP is not always straightforward.

Further, the information already published by the FDA regarding the potential harm of DEHP appears to meet the FDA's definition of when a label should be required - that is, when usage by or affecting children may be harmful to health. The population affected by the needed labeling is not insignificant. Pregnant women, women who may be pregnant, peripubertal males, and neonates constitute a large patient population for whom DEHP exposure poses the greatest concern.

We urge the FDA to craft policies that allow practitioners to implement the Public Health Notification issued by your agency. Without labeling, we find it difficult to understand how we are to carry out the FDA recommendations. As health care providers who bear the responsibility of protecting the health of patients, we urge the FDA to give practitioners the tools we need to do so.

Moreover, we urge the FDA to encourage suppliers and distributors to make information about DEHP and/or PVC readily available in catalogs and other materials used in the marketing of medical devices. Without this information, purchasers and health care providers will not be able to make informed purchasing decisions necessary for protecting the health of patients.

Regards,



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