

JOLT

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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.

Dear FDA:

Docket No. 02D-0325

We, the members of JOLT write to urge you, the Food and Drug Administration, to support your own Public Health Notification on the plasticizer di-(2-ethylhexyl) phthalate (DEHP) in medical devices, with policies that will enable 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 Our comments are offered in response to the "Draft Guidance for Industry and FDA on Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP)" recently released for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.

Justice Organizers, Leadership and Treasurers (JOLT) is a coalition of 20 faith-based organizations who promote economic justice through investments, education and action. Jolt members (1) address issues of corporate social accountability through investment screens, proxy voting and dialogue/shareholder action with portfolio companies and (2) direct capital (at below-market rates of return) to community-based initiatives that benefit underserved persons and communities. We are a member of the Interfaith Center for Corporate Responsibility. Since 1998, members have been asking health care related corporations in which they hold investments to phase out the manufacture or the use of PVC-containing or phthalate-containing medical supplies where safe alternatives are available. We have made this request because large quantities of phthalates are used to manufacture flexible PVC medical products and often the plasticizer that is used is DEHP. Most of the corporations have articulated an awareness of the problem with DEHP and PVC. Several are taking measures to move away from these substances in their products or in the use of such products.

Our dialogues with corporations lead us to believe that without an FDA requirement, many manufacturers will not notify consumers of the presence of DEHP in medical devices. Additionally, obtaining information from manufacturers as to whether or not a product contains DEHP is not always an easy task.

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 at risk from DEHP exposure.

We urge the FDA to formulate policies that allow practitioners to implement the Public Health Notification issued by your agency. Without labeling, it is difficult to understand how practitioners are to carry out the FDA recommendations. We urge the FDA to give them the tools they need to protect the health of patients.

We also believe that suppliers and distributors should be encouraged 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.

Sincerely,



Corinne Florek, OP
JOLT Coordinator

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