

Physicians for Social Responsibility

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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
Docket No. 02D-0325

RE: Comments on Draft Guidance for Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA

On behalf of the Los Angeles and San Francisco Bay Area Chapters of Physicians for Social Responsibility (PSR-LA and SF PSR) and all of PSR's California membership, we urge the FDA to require that manufacturers label DEHP-containing medical devices. We believe this will both enable health care practitioners to better protect their vulnerable patients and will assist purchasers in making informed decisions about the products they buy.

PSR-LA and SF PSR represent more than 3,000 health professionals in California. Many of our members, neonatologists and pediatricians in particular, are involved in efforts to reduce the use of polyvinyl chloride (PVC) medical devices that contain the plasticizer di-(2-ethylhexyl)phthalate (DEHP). The California PSR Chapters receive numerous requests from medical practitioners and purchasing officers for information on which medical devices contain DEHP and for information about DEHP alternatives. Information requests have increased since the FDA issued its *Public Health Notification for PVC Devices Containing the Plasticizer DEHP*.

Reviews of the scientific literature reported by a National Toxicology Program Expert Panel, peer-reviewed medical studies, and the FDA's *Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices*, have raised serious concerns in the medical community that DEHP leached from medical products during certain applications and/or in aggregate could be harmful to patient health.

PSR-LA and SF PSR are pleased that the FDA is issuing guidance to manufacturers of DEHP-containing medical devices and that the public health notification appropriately recommends the use of alternatives to DEHP-containing products when performing high-risk procedures on male neonates, pregnant women carrying male fetuses, and peripubertal males. However, due to the lack of product labeling, it will

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be quite difficult to implement the FDA's public health notification since health care providers cannot easily identify which products contain DEHP and which ones do not.

Often, purchasing officers must make individual calls to manufacturers of a particular device in order to obtain medical device material content. The absence of labeling discourages the use of alternatives, since undertaking research to identify product additives puts the responsibility on the health provider, is time-consuming, and requires research into variety of medical devices that may contain DEHP.

By requiring manufacturer labeling, nurses and physicians can easily choose safer products before treating high-risk patients.

Although the FDA draft guidance for *Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP)* recommends manufacturer labeling of DEHP-containing products, this voluntary approach does not assure manufacturers will label products or that practitioners will have enough information to make informed decisions. Without a requirement to label products, protection of patients will continue to be difficult. A voluntary approach virtually bars implementation of the FDA's own *Public Health Notification on PVC Devices Containing the Plasticizer DEHP*.

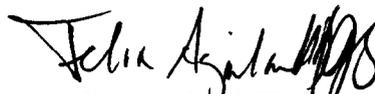
Labeling products that contain DEHP should be a simple solution to a serious concern raised by NTP and the FDA itself - exposure to DEHP from specific or combined medical treatments may be harmful to a child's health. The FDA's safety assessment and public health notification regarding the potential harm of DEHP meets its own definition for when a label should be required. The draft FDA guidance should be revised to require labeling of DEHP-containing medical devices so that health providers can respond to the concerns intelligently.

Again, on behalf of the membership of PSR in California, we request that the FDA require that manufacturers label DEHP-containing medical devices.

Sincerely,



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