



December 5, 2002

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

Re: Draft Guidance to Medical Device Manufacturers for "Medical Devices Made With Polyvinyl Chloride (PVC) Using the Plasticizer di(2-ethylhexyl) phthalate (DEHP), Docket No. 02D-0325

Dear Sir/Madam:

I am writing to request clarification on the draft guidance to medical device manufacturers regarding PVC medical devices containing DEHP. HemoCleanse develops a number of medical devices, specifically dialysis equipment, which depend on vinyl to deliver optimum results.

The Draft Guidance states that FDA is "focusing attention on the small subset of medical devices where PVC containing DEHP" would be used to treat a sensitive patient population. However, FDA's subsequent recommendations to minimize DEHP content or label products containing DEHP appear to apply to all devices containing DEHP.

As a nephrologist with over 25 years clinical experience as well as a manufacturer of vinyl medical devices, I have never encountered any cause for concern regarding patient exposure to DEHP. Dialysis patients have one of the highest chronic exposures to this compound, so I believe I would have first-hand experience with any evidence of harm. In fact, an exhaustive study of DEHP in 1996 that reviewed more than 450 previous studies concluded "an additional cancer risk by DEHP in the maximally exposed hemodialysis patients appears unlikely."¹

02D-0325

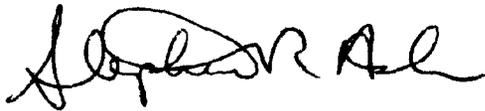
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¹ W. W. Huber, B. Grasl-Kraupp and R. Schulte-Hermann, 'Hepatocarcinogenic Potential of Di(2-Ethylhexyl) Phthalate in Rodents and Its Impact on Human Risk,' *Critical Reviews in Toxicology*, no.26(4), (1996), pp. 365-481

FDA itself acknowledges the safety profile of most DEHP-containing medical devices in the Draft Guidance that states “many devices containing DEHP are not used in ways that result in significant human exposure to the chemical.” Further, it also states “DEHP is recognized as an important chemical ingredient that affords PVC many of the physical properties that make the material optimally suited for use in many of today’s medical devices.” As such, I am confused and concerned by FDA’s apparent broad recommendation to limit the use of DEHP and request that this document be amended so that its intent is made explicitly clear.

Thank you for the opportunity to submit these comments and I look forward to reviewing FDA’s final guidance to manufacturers.

Sincerely

A handwritten signature in black ink, appearing to read "Stephen R. Ash". The signature is fluid and cursive, with the first name "Stephen" and last name "Ash" being the most prominent parts.

Stephen R. Ash, MD, FACP
Chairman and Director of R&D

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