



**MEDICAL DEVICE
MANUFACTURERS
ASSOCIATION**

Innovation Today for Better Health Care Tomorrow

December 3, 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Re: Docket No. 02D-0325; Draft Guidance Pertaining to Medical Devices Made with PVC
Containing DEHP

Dear Sir/Madam:

This letter is submitted on behalf of the Medical Device Manufacturers Association (MDMA), which represents over 160 independent manufacturers of medical devices, diagnostic products and health care information systems. For reasons explained in this letter, MDMA believes CDRH should withdraw the Draft Guidance. If CDRH continues to feel that a guidance document is necessary, then MDMA believes CDRH should issue a revised draft and allow additional opportunity for public comment. Further, if CDRH elects to pursue that course of action, MDMA urges CDRH to announce its intentions as soon as reasonably possible, so that interested parties will not expend resources commenting on a draft document that does not accurately reflect CDRH's intentions.

The Draft Guidance is causing confusion in the marketplace because of inconsistencies within the document and between the document and the underlying safety assessment. The Draft Guidance acknowledges up front that "DEHP is recognized as an important chemical ingredient that affords PVC many of the physical properties that make the material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." The Draft Guidance also acknowledges that while adverse effects have been observed in animal studies, "there are no human studies that show such effects." Further, the Draft Guidance states, "FDA recognizes that many devices with PVC containing DEHP are not used in ways that result in significant human exposure to the chemical." Elsewhere, however, the Draft Guidance contains very broad statements and recommendations that, read literally, appear to suggest that all medical devices made with PVC containing DEHP are a concern and should either be replaced or labeled.

Moreover, the overly broad statements in the Draft Guidance are not consistent with CDRH's underlying safety assessment. The concerns identified in the safety assessment pertain largely to potential hazards from use of specific medical procedures with specific potentially sensitive subpopulations (e.g., ECMO procedures applied to male neonates). The safety assessment does not demonstrate a likely safety concern for most uses of medical devices made with PVC containing DEHP.

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Under the circumstances, MDMA believes CDRH should withdraw the Draft Guidance. MDMA does not believe a guidance document in fact is necessary; MDMA believes CDRH's safety assessment and related Public Health Notification dated July 12, 2002, which also contains recommendations, are adequate to inform medical device manufacturers of the scientific issues pertaining to use of PVC containing DEHP in medical devices.

If CDRH continues to believe a guidance document is necessary, then MDMA believes CDRH should issue a new draft that more accurately reflects CDRH's intentions and allow additional opportunity for public comment, as contemplated by 21 CFR 10.115(g)(1)(v) (procedures for developing and issuing guidance documents). Further, CDRH should promptly announce that it intends to take that action, and at the same time withdraw the current draft or suspend the comment period, so that interested parties will not spend time responding to a draft that will be superseded.

If CDRH decides to issue a new draft guidance document, MDMA urges CDRH to consider the following points:

1. Any guidance document should direct attention to the medical procedures that CDRH believes pose a potential concern. A list of devices, without a clear connection to specific medical procedures, is misleading, because many medical devices are used in a wide variety of procedures, including both procedures that CDRH has identified as potentially of concern, and procedures that are expected to produce very low exposures relative to the tolerable intake (TI) calculated by CDRH.
2. Any guidance document should include greater recognition of the conservative nature of the TI in the underlying safety assessment. The TI is intended to represent a safe exposure level assuming repeated daily exposures for an extended period, which is not realistic for most medical procedures. The TI also is based on animal studies, in the absence of human data demonstrating adverse effects, and assumes that humans may be more sensitive than laboratory animals, even though primate data suggest the opposite. For these reasons, even if use of a medical device in a particular procedure might result in exposures above the TI on the days that the procedure is performed, that does not mean there is a significant health risk to the patient.
3. Any guidance document should state clearly that if medical device manufacturers consider alternatives to PVC made with DEHP, they should give adequate consideration to all performance, exposure or safety issues associated with any alternative materials that might be considered. As reflected in the DEHP safety assessment, DEHP has undergone extensive testing and there is an enormous amount of scientific information available to support that safety assessment. Medical device manufacturers should be cautioned about moving to alternative products that might lead to



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decreases in performance and exposures to substances about which considerably less is known.

Thank you for your consideration of this letter and MDMA's requests. MDMA respectfully urges prompt action by CDRH to alleviate the confusion in the marketplace caused by the overly broad statements in the Draft Guidance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Larry R. Holden", written over a horizontal line.

Larry R. Holden

President,

Medical Device Manufacturers Association