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November 7, 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02D-0325: Medical Devices Made with Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA

Dear Sir/Madam:

I am writing on behalf of AdvaMed's PVC Working Group. In this letter, I will address some of our more general and immediate concerns regarding the subject draft guidance. Before the deadline, we will also supplement this letter with more specific comments and recommendations.

The draft guidance begins appropriately by acknowledging that "Although the toxic and carcinogenic effects of DEHP have been demonstrated in laboratory animals, there are no human studies that show such effects" and that "many devices made with PVC containing DEHP are not used in ways that result in significant human exposures to the chemical." It further states that devices used in Neonatal Intensive Care Units should be a primary focus. However, it does not maintain this focus through the document with the questions and responses on what FDA is recommending. Therefore, many persons have apparently concluded from the draft guidance that FDA is seeking replacement or labeling of DEHP-plasticized PVC for **all** uses.

I AdvaMed, the Advanced Medical Technology Association, (formerly the Health Industry Manufacturers Association) represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the \$68 billion health care technology products consumed annually in the United States, and nearly 50 percent of \$159 billion purchased around the world annually

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Many customers of both device companies and, we understand, PVC suppliers have expressed concern over many devices containing PVC—even those not used in therapies associated with the agency's specified patient populations of concern. In addition, we believe it likely that many users do not distinguish between DEHP-plasticized PVC and PVC containing other plasticizers. Furthermore, many customers do not distinguish among draft guidance, final guidance, and regulations. Thus, there is undue concern about DEHP-plasticized PVC products—including those that FDA views as benign.

We recommend that FDA withdraw the draft guidance or issue clarifying language prior to the close of the comment period. We believe that it is particularly important for FDA

to make clear that its concern is with the increased risk of DEHP exposure during specific procedures affecting subsets of well-defined patient populations and to direct recommendations at those procedures.

If the draft remains as written, manufacturers may have to take costly steps to quell customers' concerns, possibly even before the agency issues final guidance. These steps could include:

- Adding costly labeling for an unproven risk from PVC/DEHP
- Replacing DEHP-plasticized PVC with other material(s) in applications where potential risk has been identified and in which the performance of the alternative material(s) may be neither equal to nor better than the original plasticizer; nor its use be as well studied and documented

Other potentially negative aspects to a broad move to other materials include:

- An industry-wide material change would lend credence to the claims of those who have raised objections to the use of DEHP-plasticized PVC. Without a solid scientific basis for the change, the industry and the agency, which both expend significant resources to maintain high scientific standards, would be setting an unfortunate precedent likely to reap negative future rewards.
- Mechanisms not currently identified could reduce the level of patient safety. DEHP-plasticized PVC has a long history of successful clinical application. A similar level of information is not likely to accompany any new material.
- Alternative materials may not deliver the same level of performance. If they did, manufacturers would already be using them.

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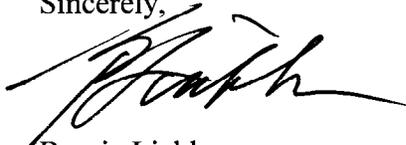
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- Alternative materials may add cost to products. Not only may customers object to more expensive products, but also the increased cost would further burden our health care system for little or no benefit.

AdvaMed appreciates the opportunity to comment on this document. We hope that these general comments will assist the agency in developing a more effective document. Please contact me if you have any questions or would like further information.

Sincerely,

A handwritten signature in black ink, appearing to read "Bernie Liebler", written in a cursive style.

Bernie Liebler
Director, Technology and
Regulatory Affairs