January 5, 2001

Mr. Gene Livingston
Attorney at Law
Livingston & Mattesich
1201 K Street, Suite 1100
Sacramento California 95814

Dear Mr. Livingston:

The Office of Environmental Health Hazard Assessment (OEHHA) has completed its review of the February 22, 2000 petition of the Advanced Medical Technology Association (formerly the Health Industry Manufacturers Association) pertaining to Proposition 65 warning regulations for medical devices. OEHHA has also closely reviewed oral comments received at the September 21, 2000 workshop on the petition, and written comments submitted to OEHHA in conjunction with the workshop.

We believe there is merit to the development of a regulation that addresses the administering of Proposition 65 warnings to an unconscious patient, a patient undergoing an urgent medical procedure, and a person who is legally incapable of giving consent. We do not believe current regulations properly recognize the unique circumstances involving the use of medical devices on these types of patients. OEHHA will begin drafting regulations this year in this area pursuant to the requirements of the Administrative Procedure Act. All interested members of the public, of course, will have an opportunity to review and comment on the draft regulations prior to any final regulatory action by OEHHA.

OEHHA must respectfully deny the other requests in the petition for generalized warning regulations pertaining to all medical devices. While we are sympathetic to the challenges faced by medical device manufacturers in complying with warning regulations, we believe the petition is overly broad and does not provide an adequate basis for creating special and unique warning rules for a large number of medical device products.

In your presentation at the September 12, 2000 workshop, you stated there are more than 4,000 separate categories of medical devices. These devices undoubtedly are used in many different medical procedures. We presume these devices may contain various listed chemicals and that the types and levels of exposure to these chemicals vary widely, depending on the device and the treatment being administered. The variety of chemicals and exposure scenarios among these 4,000 categories of medical devices may mirror the variety found in all products

that are subject to Proposition 65 warning requirements. After carefully studying the petition and the oral and written comments, we are not convinced that all of these medical device products require special regulations that treat them differently than other products falling within the jurisdiction of Proposition 65.

The petition contains no discussion of specific devices, the way they are used, listed chemicals they contain, the way patients may be exposed to these chemicals, and the factors that make it overly burdensome for manufacturers of those products to comply with current Proposition 65 warning requirements. The presentations at the September 21, 2000 workshop by representatives of device manufacturers were helpful in providing a general understanding of how medical devices are distributed and used. In fact, the discussion of the use of medical devices in emergencies was convincing in demonstrating that current warning regulations are insufficient to deal with situations involving unconscious patients and those needing emergency medical treatment. However, the presentations still discussed the distribution and use of medical devices in a very general manner. We cannot infer that special warning regulations are needed for all medical devices because of the way some medical devices are used, for example, in kidney dialysis or emergency medical treatment. Similarly, we cannot infer that the lack of direct contact between medical device manufacturers and patients as discussed in your petition and presentations makes the providing of warning uniquely problematic that special warning requirements are needed for all medical devices.

Thank you for your continuing interest in Proposition 65 matters. If you have any questions, please call me at (916) 324-2831.

Sincerely,

Val F. Siebal
Chief Deputy Director