



**Advanced Medical Technology Association Statement
at the October 27, 2009
Public Hearing on the Advisability of Requiring Disclosure of Free Samples of
Prescribed Products Given to Vermont Health Care Providers**

Good Morning. My name is Thomas Tremble. I am Associate Vice President, State Government Relations with the Advanced Medical Technology Association or AdvaMed. AdvaMed is a national association representing more than 1,300 medical device manufacturers. I appreciate the opportunity to comment on the advisability of requiring disclosure of free samples. I would like to address the issue as it relates to medical devices.

I think it may be helpful for me to provide you with a better understanding of device sampling.

Medical devices cover a broad range of products including bandages, catheters, surgical tools, artificial knees and hips, as well as large laboratory equipment and diagnostic imaging. Devices are unique in that they may be used by both patients and providers. Therefore, it is appropriate that device samples be made available both for evaluation by patients and providers, as well as to allow both patients and providers to gain a better understanding of their clinical utility prior to patient use.

It is generally recognized that there are three types of product samples in the medical device industry:

Direct to Patient Single Use Disposable Devices

Companies provide physicians with samples of single-use disposable devices, such as advanced wound care bandages and catheters. Since a patient's condition might not respond to a particular device, drug, or other

treatment, a physician may want to provide a patient with samples to evaluate the patient's response.

Demonstration Devices

Generally, when preparing a patient for surgery, the physician will try to alleviate their apprehension by describing the procedure, its length, the type of anesthesia to be used, etc. If the patient is to receive an implantable device, such as an artificial knee or hip, they will want to show the patient a model of the implant while they describe the implantation procedure.

Allow me to pass around a sample of a replacement hip. If you look closely at the ball, you can notice that it has SAMPLE and "Not for Implant" stamped on it. A demonstration device is not intended for actual clinical use, but rather to educate the patient and facilitate optimal medical decision-making.

Evaluation Units

The third type of sampling occurs with large medical equipment, where a company will provide the equipment for a short-term fixed period of time to allow a practitioner to evaluate the appropriateness of the equipment for their practice. Providing evaluation units is analogous to taking a car for a test.

In each of these three types of sampling, devices are provided directly to patients or care is provided to the patients with the device so that the physician can evaluate the appropriateness of the device for a particular patient or group of patients. So, while the demonstration devices and evaluation units support and contribute to patient care, they also enhance practitioners' understanding of the device's clinical utility.

To ensure that medical device sampling is in the best interests of patient care, many companies have policies on sampling, some health care facilities and medical practices have policies governing the use of product samples, and AdvaMed's Code of Ethics has provisions that address the medically appropriate dispensing of device samples.



The current version of our Code of Ethics, which took effect on July 1 of this year, recognizes that device sample products are appropriate for evaluation and demonstration purposes and can benefit patient care in many ways.

Our Code of Ethics sets out pertinent guidance to medical device companies to ensure the propriety of sampling practices. For example, the Code states that companies should provide health care professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products, and furnish samples only to the extent necessary to allow a reasonable evaluation.

Although our Code doesn't have the force of law, it has been widely recognized by professional societies and even prosecutors as appropriate industry guidance. Further, with its latest revision, it now includes a certification process whereby companies that adopt the Code are asked to submit an annual certification that they have adopted the Code and have an effective compliance program.

As of January 1, 2010, our web site will include a listing of those companies that have certified that they are in compliance.

In all cases, samples are provided to educate patients, ensure use of the most appropriate technology and otherwise enhance patient care and do not provide any direct benefit to the provider or institution.

There is legitimate concern that the reporting and disclosure of device samples, even if reporting is limited to the Attorney General, could give the mistaken impression of an inappropriate relationship and therefore discourage the use of beneficial device samples. Further, the administrative burden imposed by having to track items of de minimis value might disincite companies from continuing this beneficial practice for health care outcomes.



In Act 59, the Legislature excluded “samples of a prescribed product...” from the general prohibition on gifts to health care providers. However, the disclosure provisions on the legislation did not retain the “prescribed product” term and made a distinction between prescription drugs and devices.

The statute and subsequent guidance recognized the appropriateness of excluding product samples from reporting. The same rationale applies to medical device samples. We propose that the Attorney General and the Commission on Health Care Reform should recommend to the Legislature that the exclusion for the reporting of sample products be extended to the three categories of medical device samples.

Thank you for your consideration of our concerns.