

701 Pennsylvania Avenue, NW, Suite 800
Washington, DC 20004-2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

Christopher L. White, Esq.
Executive Vice President, General Counsel
and Assistant Secretary

Direct: 202 434 7217
cwhite@AdvaMed.org



January 12, 2010

Wendy Morgan, Esq.
Assistant Attorney General
Office of the Vermont Attorney General
109 State Street
Montpelier, VT 05609-1001
wmorgan@atg.state.vt.us

Dear Ms. Morgan:

I write in follow up to our discussion last week concerning medical device sampling interactions between device manufacturers and health care providers in connection with your office's Report to the Legislature. We very much appreciate your attention to the testimony on device sampling delivered by my colleague Thomas Tremble, on October 27, 2009.

First, as we discussed, our industry adopted a substantially revised Code of Ethics, guiding ethical collaborations and interactions with health care professionals, effective July 1, 2009. Section XII of the revised Code provides specific guidance regarding the provision of sample products to health care professionals. This Code provision seeks to preserve beneficial interactions fostering patient access to the most advanced medical technologies and facilitate the safe and effective use of medical technology. See, <http://www.advamed.org/MemberPortal/About/code/>.

You also raised questions of a more specific nature concerning medical device sampling, which I address below:

1. Single use, disposable medical device samples that incorporate a drug or biologic.

You asked whether there exist any single use, disposable medical device samples that incorporate a drug or biologic. While, during our call, I was not immediately aware of a specific product, I indicated that the frontiers of medical technology are expanding rapidly, and the preservation of bona fide sampling practices are critical to patient awareness and access to new medical technology, including any potential single use, disposable medical device that might incorporate a drug or biologic now or in the future. I also offered to quickly coordinate with our membership to provide a more specific response.

In short, yes, there currently exist certain single use, disposable medical devices that incorporate a drug or biologic. Two examples include catheters coated with antibiotics and antimicrobial wound care dressings. Consistent with their internal sampling policies, companies may provide samples of such products for the same reasons they would provide samples of other device products.

However, this is a complicated area, and I thought it would be helpful to provide some brief background on two points to clarify this response:

First, as we discussed, in any discussion of medical product types, it is important to define the relevant terms in reference to the FDA's technical product review authorities. For example, products that might be considered "medical supplies" (or by other terms) in an insurance coverage context, or in general usage, might fall within the FDA's definition of a "medical device." For purposes of this response and our earlier testimony, our use of "medical device" and "medical technology" refers to products subject to FDA device authorities. For this reason, we encourage your office to align its use of "drug," "medical device," "biologic," among others, in the Report with the relevant FDA definitions to avoid any confusion.

Second, your question concerns some technologies known in the industry and treated by the FDA as "combination products." Combination products are brought to market under the device regulations, the drug regulations or the biologic regulations, depending on a determination of the product's primary mode of action. A combination product could include for example, a product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity. In responding to your question above, I address only those combination products that are brought to market under the device regulations (i.e., based on their primary mode of action). AdvaMed's response should not be read to address combination products regulated by FDA pursuant to non-device authorities.

2. FDA Definition of Device Sample

I also wished to confirm that I am not aware of any FDA definition of a device "sample." FDA's regulatory approach is to review technologies falling within its medical device jurisdiction. Products then may only be marketed in a manner consistent with FDA's clearance and approved labeling. The sampling practices described in our testimony, in our Code of Ethics, and above are limited to FDA cleared products only.

Wendy Morgan, Esq.
January 12, 2010
Page 3 of 3

Thank you again for your interest in understanding the sampling practices in our industry,
and please do not hesitate to call or reply with any further questions.

Very truly yours,

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

Christopher L. White
Exec. VP, General Counsel and Assistant Secretary

Cc: Thomas Tremble, AdvaMed