



AdvaMed

Advanced Medical Technology Association

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Statement to the FDA Risk Communication Advisory Committee

My name is Jeffrey Secunda. I am an Associate Vice President for Technology and Regulatory Affairs with AdvaMed, the Advanced Medical Technology Association. AdvaMed is the leading trade association representing the manufacturers of medical devices, diagnostics, and health information systems. I appreciate this opportunity to present the device industry's perspective at the first public meeting of the Risk Communication Advisory Committee.

AdvaMed applauds Commissioner von Eschenbach for establishing the Risk Communication Advisory Committee to advise FDA in effective communications to the public to help facilitate effective and safe use of all FDA regulated products.

Risk communication is a core activity in the device industry. The industry seeks to communicate risk and benefit information about our products to enable people to make informed independent decisions about these products. The industry goes to great lengths to develop the expertise necessary to evaluate customers' ability to understand complex information and instructions. Our customers include the healthcare professional as well as the patient. In fact, medical device communication stakeholders include all those who prescribe, purchase, use, and assist in the use of our products.

It is for these reasons that we feel that industry representatives, with appropriate risk communication credentials, should be available to the core advisory committee to provide experiential insight on communicating with device stakeholders. Although the charter of the Risk Communication Advisory Committee does allow for the inclusion of industry representation by invitation; the available representatives are limited to existing members of other FDA Advisory Committees. The industry representatives on these existing

Advisory Committees are chosen on the basis of their knowledge of FDA regulation and the products under consideration by the particular Advisory Committee. Restricting the pool of industry representatives to those from existing Advisory Committees will severely limit the Risk Communication Advisory Committee interaction with risk communication experts from the device industry.

AdvaMed recommends that FDA develop a pool of risk communications experts representing the unique knowledge and experience of the companies who develop and market the various products represented by the five FDA Centers. These representatives would be vetted in the same fashion as other industry representatives to FDA Advisory Committees. Risk communications experts from industry would be non-voting and available to the core committee on an as needed basis. We urge the Commissioner to consider this recommendation and to identify industry representatives using the same thoughtful criteria that has been applied to identifying the others members of the Risk Communication Advisory Committee.

Standard template for Press Releases

As stated earlier, risk communications is a core activity of the device industry. When it becomes necessary to inform device users of a problem, the industry strives to develop useful information that is directed to the affected population. To be useful the communication should include the nature of the problem, the likelihood and severity of the problem, and the actions needed to ameliorate the problem. In those instances when no specific action is indicated, the communication should be carefully crafted.

Exaggeration of risk to the target population or misinforming unaffected populations could discourage appropriate use of beneficial devices, drugs, or biologics.

Press releases and other vehicles of communication should use accurate and understandable language. Terms such as “Notice,” “Correction,” and “Removal” coupled with appropriate adjective such as “Urgent” or “Critical” are precise and widely understood. Although the term “Recall” may have its place in the Agency lexicon, it is understood by the public to be synonymous with “Removal.” “Recalls” affecting foods

and drugs, which have a limited useful lifetime, generally do mean removal. Devices however fall into several use categories such as:

1. Patients with long term implants
2. Patients who use devices without medical supervision
3. Patients having a transient experience with device operated by a health professional
4. Patient with no direct contact with device

I urge the Committee to consider these use categories when considering the structure and content of press releases intended to inform the affected public of device problems.

A press release is an effective tool useful for reaching a very broad population very quickly. Press releases should not be the automatic response to every Class I problem unless the affected population can not be reached effectively by more precise methods such as letters to the patient or prescribing physician. Furthermore, delayed or repeated press releases can undermine the effectiveness of a focus communication plan. For instance, a company may send letters to the affected population in one month only to have a press release required by the Agency several months later. The result is confusion amongst all segments of the patient population whether or not they are affected by the problem and a tidal wave of inquires to physicians and companies who similarly may not be involved with the specific device problem.

In summation I urge the Committee to consider the very real danger of discouraging the appropriate use of beneficial devices do to the overly broad communication effect of the press release.

Thank you.