**ADVAmed Guiding Principles for Product Communications**

The advanced medical technology industry (the “industry”) develops, manufactures, and markets medical products, technologies, and related services used to diagnose and treat health conditions and disabilities in order to enable patients to live longer and healthier lives. The industry is committed to supporting Health Care Professionals (“HCPs”), patients, and the public health by providing information on the safe and effective uses of our products, in accordance with the approved or cleared uses set forth in product labeling. As the Food and Drug Administration (“FDA”) has noted, the public health can be served when HCPs receive truthful and non-misleading information on both approved and unapproved uses of products.

**Restrictions on Off-Label Promotion**

The FDA regulates the labeling and promotion of medical devices and diagnostics (“products”) in the United States. Under FDA regulations and enforcement policies, these products may only be labeled (including promotional labeling) and advertised in a manner consistent with FDA approved or cleared uses. Because the Food, Drug, and Cosmetic Act prohibits manufacturers from misbranding their products, this area has become an intense enforcement interest of FDA, the U.S. Department of Justice and many State Attorneys General. The industry is strongly committed to compliance with appropriate limitations¹ on product promotion established by FDA to provide assurance of product safety and effectiveness, and supports reasonable and responsible enforcement efforts aimed at stopping clearly unlawful off-label product promotion. The industry is also supportive of the FDA’s efforts to clarify its regulations and guidance about the communication of truthful and non-misleading medical information in a manner consistent with the interest of public health and the First Amendment.

**Appropriate Off-Label Use**

An HCP’s off-label use of a product must not be confused with off-label promotion of such product by its manufacturer or its distributor. HCPs may generally use a product in their practice of medicine for any use that they determine is in the best medical interests of their patient. As recognized under U.S. law² and by the FDA itself³, off-label use of these products can be an important part of medical practice and may even

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¹ Any such FDA limitations must, of course, be authorized under the Federal Food, Drug, and Cosmetic Act, or other governing law, and both the regulations and the law must not infringe protections provided by the First Amendment.

² “Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.” 21 U.S.C. § 396

³ For example, the FDA recognized in its Good Reprints Guidance “the important public health and policy justification supporting dissemination of truthful and nonmisleading medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare entities . . . . These off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care. Accordingly, the public health may be advanced by healthcare professionals’ receipt of medical journal articles and medical or scientific reference publications on unapproved uses of approved or cleared medical products that are truthful and not misleading.” (Citation to FDA Good Reprints Practice Guidance).
constitute a medically recognized standard of care. In fact, public health agencies, such as the Centers for Medicare and Medicaid Services (“CMS”), have authorized reimbursement of off-label uses of approved products where such use is recognized under generally accepted medical standards.

Generally, an off-label use is a use of an approved or cleared product that is not consistent with the product's FDA approved labeling or statement of intended use. The regulatory history of a product and/or similar products can influence whether a particular use of a product is considered an off-label use. Examples of uses the government has identified as off-label include, but are not limited to:

- Use in a disease state that is different from or broader than the approved indication;
- Use in a different patient population;
- Use in a different anatomical location;
- Use of a procedural technique that is inconsistent with the technique described in the labeling;
- Use of a product for a length of time that is different than described in the labeling; or
- Use of a product at a different point in time during disease progression or treatment continuum.

To provide high-quality care and to safely use available products in the best interest of their patients, HCPs must have adequate access to information about these products. When these products are used for on-label purposes, HCPs have full access to a wide range of information and educational materials from manufacturers who can disseminate this information through such traditional means as product labeling, advertising, scientific presentations and product training. Due to FDA limitations, however, HCP access to information from industry about off-label uses is more restricted. HCPs must look to alternative sources of information to gain sufficient, up-to-date knowledge before electing to use these products in an off-label manner. In the case of medical devices and diagnostics, some of that information may have been developed or collected by the industry. Access to needed information relating to on- or off-label uses through appropriate scientific exchange with industry representatives is critical to an HCP’s ability to exercise his or her medical judgment in the best interest of their patients.

**BONA FIDE EXCHANGES OF SCIENTIFIC, CLINICAL, AND TECHNICAL INFORMATION**

In recognition of the responsibility of HCPs to use products in ways that can best benefit their patients, the public health is advanced by HCP access to truthful and non-misleading scientific, clinical, and technical information on unapproved uses of approved or cleared products. HCPs obtain much of this important information through appropriate scientific exchanges directly with, or supported by, industry. These exchanges include, but are not limited to, responses to unsolicited requests for clinical information about unapproved uses of a product; responses to requests for standard product technical support in connection with patient care involving unapproved product uses; proper dissemination of peer-reviewed medical journal articles on unapproved uses; and financial support of independent continuing medical education (CME) programs free from industry influence.

When engaging in scientific exchanges with HCPs on both approved and unapproved uses, industry must ensure that these activities are appropriately substantiated to avoid enforcement risk. This risk is highly dependent on the facts and circumstances of the interaction. Companies should implement appropriate controls to minimize these risks occurring in the following areas:

- Sales personnel interactions with HCPs;
- Support of independent Continuing Medical Education (“CME”);
• Participation in appropriate forums for scientific exchange with HCPs, medical professional societies, and/or payors
• Consultative meetings with HCPs or medical professional societies;
• Provision of product specific training and education;
• Sponsorship and publication of non-clinical and clinical research;
• Dissemination of promotional materials.
• Technical and Clinical Support

INDUSTRY PRINCIPLES

Increasingly, medical devices and diagnostics deliver value through technology that requires the sharing of technical and clinical information with HCPs and/or patients to provide the best patient outcomes. The direct dissemination of product information may be supplemented by the provision of technical and clinical support in the delivery of health care services to patients. The need for such technical and clinical support by company representatives, who have the benefit of deep product knowledge, occurs with both approved and unapproved uses of products.

The industry is committed to striking an appropriate balance between the legal restrictions on their promotional and marketing activities and the needs of HCPs for accurate and helpful information when they choose to use products to help their patients in ways that are not covered by the approved labeling. The following principles regarding general industry-HCP interactions recognize industry’s responsibility to provide medical and scientific information to assist in achieving positive patient outcomes. The industry is committed to assuring compliance with these principles and applicable law.

1. Promotional communications must be consistent with the FDA regulatory approval or clearance of that product.

2. Non-promotional communications may contain truthful and non-misleading scientific information, consistent with the weight of credible evidence, relating to unapproved uses of approved or cleared products. These communications may include, for example, dissemination of peer-reviewed medical journal articles and textbooks, responses to unsolicited requests for clinical information or technical support, or responses to unsolicited questions arising in the context of company-conducted product training and education.

3. Scientific information and non-promotional communications that contain off-label use information may be provided by trained professionals with appropriate medical, scientific or technical expertise to support HCPs who choose to use the product in an off-label manner in the best interests of patients. Information may also be provided consistent with FDA’s Good Reprint Practices. Importantly, such information must be truthful, non-misleading, and consistent with the weight of credible evidence on an off-label use of the product.

4. AdvaMed members support continued dialogue with the FDA to establish clear, unambiguous guidelines and safe harbors for industry to rely on in providing appropriate medical information that meets the needs of HCPs who seek it out in their practice of medicine.

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