Alliance of Specialty Medicine

Sound Policy. Quality Care.

May 2, 2014

Leslie Kux, Assistant Commissioner for Policy
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Submitted electronically via regulations.gov

Re: Revised Draft Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices

Dear Assistant Commissioner Kux:

The Alliance of Specialty Medicine (Alliance) is a coalition of medical specialty societies representing more than 100,000 physicians and surgeons dedicated to the development of sound federal healthcare policy that fosters patient access to the highest quality specialty care. Today, we are writing to express our concern with the US Food and Drug Administration's (FDA) revised "*Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices*."

While the Revised Draft Guidance attempts to clarify existing guidance with respect to FDA's recommended practices, offering recommendations for manufacturers on best practices for disseminating scientific and medical journal articles and scientific and medical reference texts we are concerned that it inappropriately restricts specialty physicians' access to scientific information provided by manufacturers on the safe and effective use of medical products, including drugs, devices and biologics, which is an important part of specialty medicine that improves patient care and drives innovation in clinical practice.

FDA has long recognized that physicians may use products "off-label," even if manufacturers cannot promote those same uses. However, disseminating truthful, non-misleading scientific information on the medically accepted alternative uses of approved medical products, is not viewed as promotional by our organizations. As discussed in our Position Statement on Physician-Directed Applications (see attached)

> *"To enhance patient care, physicians must have unrestricted access to truthful, non-misleading information about the benefits and risks of all therapies available for treatment, including medically accepted alternative uses of approved prescription drugs, biologics, and/or devices. Manufacturers must be able to provide adequate directions for use of both approved and medically accepted alternative indications of approved medicines and treatments, along with adequate disclosures regarding risks and the limitations of scientific understanding.*
>
> *Provided there is prominent disclosure that FDA does not approve such use, limitations on communications should only be related to patient risk based on factors including the approval status of the medicine, general medical acceptance of the treatment, and the level of scientific sophistication of the audience."*

Toward that end, we urge the FDA to ensure that access to scientific information from manufacturers on the safe and effective approved and unapproved use of medical products is not disrupted when the guidance is finalized.

Thank you for considering our comments and concerns. Should you have any questions, please contact Emily L. Graham, RHIA, CCS-P, at egraham@hhs.com.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society of Cataract & Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
National Association of Spine Specialists
Society for Cardiovascular Angiography and Interventions

Encl: Alliance of Specialty Medicine Position Statement – Physician-Directed Applications