June 29, 2015

Stephen Ostroff, MD
Acting Commissioner
U.S. Food and Drug Administration
Docket No. FDA-2013-N-0500
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted via email to: Stephen.Ostroff@fda.hhs.gov

Dear Acting Commissioner Ostroff,

We are writing to express support for addressing barriers to communication that exist between physicians and drug and device manufacturers. To enhance patient care, physicians must have unrestricted access to information about benefits and risks of all therapies for treatment, including medically accepted alternative uses of approved drugs, biologics, and/or medical devices.

Physician-directed applications, "off-label" uses, or medically accepted alternative uses are an important component of the evolving practice of medicine. It is not uncommon for "off-label" uses to become standard of care. In fact, for certain subgroups (such as children and minorities) and conditions (such as certain types of cancer and rare diseases), an "off-label" therapy may be the accepted standard of care. In addition, important data about drugs and devices may be consistent with the FDA-approved use, but nevertheless exist outside of FDA-approved labeling. We are concerned that the companies that research, develop, and bring these treatments to market may not proactively communicate about useful information that they hold that is outside of the FDA-approved labeling. This may include important data related to subpopulations such as minorities, women, and any other groups who are traditionally underrepresented in clinical trials.

It is the mission of physicians in all specialties to use the safest and most effective means to assist patients in health maintenance, disease prevention, effective disease management and accessing curative therapies. Most of these endeavors are accomplished with the use of treatment modalities that are not only the standard of care but also FDA approved. However, in instances and circumstances where no definitive FDA-approved indication is available, the use of medically accepted alternative uses of approved medicines is often necessary.

Non-approved use of medical products has actually become the standard of care in the treatment of many orphan diseases and also frequently used when standard, accepted treatments fail in common diseases. For example, in the specialty of rheumatology, there are many diseases where little or no scientific or clinical information is present regarding the treatment of certain autoimmune diseases, including Sjögren's syndrome, Behcet's disease, many forms of vasculitis, inflammatory muscle diseases, scleroderma, calcium pyrophosphate deposition disease and other conditions. Despite the lack of FDA approved indications, those patients still require treatment and, as their physicians, we endeavor to use whatever information is available to help with informed decision-making. For instance, many non-approved indications can be found in standard textbooks of medicine and surgery in all specialties and subspecialties for patients of all ages and are the generally accepted standard of medical care.

Physicians are savvy consumers of scientific information, and FDA regulations should not restrict access to the latest scientific information, provided that it is truthful and not misleading. Manufacturers must be able to provide adequate directions for use of both approved and medically accepted alternative indications of approved drugs, biologics, and medical devices, along with appropriate disclosures regarding risks and limitations.

We encourage the Agency to work constructively with all stakeholders to ensure physicians have up-to-date scientific information and can provide the most effective, evidence-based care. We respectfully request that FDA begin a process this year to revise its regulations to allow companies to share truthful information about drugs and devices with healthcare professionals and payers – even if such information exists outside of FDA-approved labeling. Some of the undersigned organizations are member of the Alliance of Specialty Medicine, which has a longstanding position on off-label communication. For reference, that policy paper is attached in its entirety.

Please contact any of the undersigned organizations should you have any questions or require additional information.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
GLMA: Health Professionals Advancing LGBT Equality
National Black Nurses Association
National Council of Asian and Pacific Islander Physicians
National Hispanic Medical Association
National Medical Association
Salud USA
Society for Cardiovascular Angiography and Interventions
Society for Excellence in Eyecare

ATTACHMENT