The Honorable Michael C. Burgess, MD United States House of Representatives 2336 Rayburn House Office Building Washington, DC 20515

Dear Dr. Burgess:

The undersigned physician organizations representing both national specialty medical societies and state medical societies are writing to express our strong support for H.R. 293, which would clarify that certain applicable manufacturer transfers of value to support independent medical educational programs and materials are exempt from reporting under the Physician Payments Sunshine Act (Sunshine Act). Passage of this bill is urgently needed to remedy onerous and burdensome reporting obligations imposed by the Centers for Medicare and Medicaid Services (CMS) that have already chilled the dissemination of medical textbooks, peer-reviewed medical reprints and journals, and to avert a similar negative impact on access to independent certified and/or accredited continuing medical education (CME). H.R. 293 would ensure that efforts to promote transparency do not undermine efforts to provide the most up-to-date independent medical knowledge, which improves the quality of care patients receive through timely dissemination of medical knowledge.

The Sunshine Act was designed to promote transparency with regard to payments and other financial transfers of value between physicians and the medical product industry. As part of this provision, Congress outlined 12 specific exclusions from the reporting requirement, including "[e]ducational materials that directly benefit patients or are intended for patient use." In its interpretation of the statute, CMS concluded that medical textbooks, reprints of peer reviewed scientific clinical journal articles, and abstracts of these articles are not directly beneficial to patients, nor are they intended for patient use. This conclusion is inconsistent with the statutory language on its face, congressional intent, and the reality of clinical practice where patients benefit directly from improved physician medical knowledge.

The importance of up-to-date, peer reviewed scientific medical information as the foundation for good medical care is well documented. Scientific peer-reviewed journal reprints, supplements, and medical text books have long been considered essential tools for clinicians to remain informed about the latest in medical practice and patient care. Independent, peer reviewed medical textbooks and journal article supplements and reprints represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients.

The Food and Drug Administration's (FDA) 2009 industry guidance, titled "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices," underscores the importance of this scientific peer reviewed information. The FDA noted the "important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications." H.R. 293 clarifies that the Sunshine Act was designed to support the dissemination of this type of educational material. We also support language in the bill clarifying that CME that meets the standard for independence must be exempt from Sunshine Act reporting.

The Honorable Michael Burgess May 29, 2015 Page 2

We strongly support passage of H.R. 293 and commend your leadership on this issue. The Institute of Medicine and other major stakeholders have repeatedly expressed concern with the length of time required for clinically validated discovery to become part of regular clinical practice. The Sunshine Act was not passed to limit or construct additional barriers to the dissemination of new medical knowledge that improves patient health outcomes. H.R. 293 is needed to ensure patients benefit from the most up-to-date and relevant medical knowledge.

Sincerely,

American Medical Association Aerospace Medical Association AMDA – The Society for Post-Acute and Long-Term Care Medicine American Academy of Allergy, Asthma & Immunology American Academy of Dermatology Association American Academy of Emergency Medicine American Academy of Facial Plastic and Reconstructive Surgery American Academy of Family Physicians American Academy of Home Care Medicine American Academy of Hospice and Palliative Medicine American Academy of Ophthalmology American Academy of Otolaryngology—Head and Neck Surgery American Academy of Pain Medicine American Academy of Physical Medicine and Rehabilitation American Association of Clinical Endocrinologists American Association of Neurological Surgeons American Association of Neuromuscular & Electrodiagnostic Medicine American Association of Orthopaedic Surgeons American Clinical Neurophysiology Society American College of Allergy, Asthma and Immunology American College of Cardiology American College of Chest Physicians American College of Emergency Physicians American College of Gastroenterology American College of Mohs Surgery American College of Occupational and Environmental Medicine American College of Osteopathic Family Physicians American College of Osteopathic Internists American College of Osteopathic Surgeons American College of Phlebology American College of Preventive Medicine American College of Radiology American College of Rheumatology American College of Surgeons American Congress of Obstetricians and Gynecologists American Gastroenterological Association American Geriatrics Society American Medical Group Association

American Osteopathic Association American Psychiatric Association American Society for Clinical Pathology American Society for Dermatologic Surgery Association American Society for Gastrointestinal Endoscopy American Society for Radiation Oncology American Society for Reproductive Medicine American Society for Surgery of the Hand American Society of Addiction Medicine American Society of Anesthesiologists American Society of Bariatric Physicians American Society of Cataract and Refractive Surgery American Society of Clinical Oncology American Society of Dermatopathology American Society of Echocardiography American Society of Neuroradiology American Society of Nuclear Cardiology American Society of Plastic Surgeons American Society of Transplant Surgeons American Thoracic Society American Urological Association College of American Pathologists Congress of Neurological Surgeons Council of Medical Specialty Societies **Endocrine Society** Medical Group Management Association

International Society for the Advancement of Spine Surgery
Medical Group Management Association
National Association of Medical Examiners
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Hospital Medicine
Society of Thoracic Surgeons

Medical Association of the State of Alabama
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association Inc
Medical Association of Georgia
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society

Kentucky Medical Association Louisiana State Medical Society Maine Medical Association MedChi, The Maryland State Medical Society Massachusetts Medical Society Michigan State Medical Society Minnesota Medical Association Mississippi State Medical Association Missouri State Medical Association Montana Medical Association Nebraska Medical Association Nevada State Medical Association Medical Society of New Jersey New Mexico Medical Society Medical Society of the State of New York North Carolina Medical Society North Dakota Medical Association Ohio State Medical Association Oklahoma State Medical Association Oregon Medical Association Pennsylvania Medical Society Rhode Island Medical Society South Carolina Medical Association South Dakota State Medical Association Tennessee Medical Association Texas Medical Association **Utah Medical Association** Vermont Medical Society Medical Society of Virginia Washington State Medical Association West Virginia State Medical Association