



Sound Policy. Quality Care.

May 2, 2017

The Honorable Morgan Griffith
2202 Rayburn House Office Building
Washington, D.C. 20515

RE: Support for the “Medical Product Communications Act of 2017” (H.R. 1703)

Dear Congressman Griffith:

The Alliance of Specialty Medicine (the “Alliance”) represents more than 100,000 specialty physicians. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

The undersigned members of the Alliance are writing to thank you for your introduction of H.R. 1703, the Medical Product Communications Act of 2017. The current regulatory paradigm to determine a product’s “intended use” by the Food and Drug Administration (FDA) has created uncertainty among manufacturers, which in turn hampers the free exchange of information.

For some specialties, a so-called “off-label” use – or use of a medicine or device for an indication not approved by FDA – is the standard of care. As such, the free flow of data on such off-label uses is critical to advancement of the practice of medicine. Unfortunately, the current way FDA determines the “intended use” has a negative impact on such scientific exchange.

Your legislation would establish clear parameters on what constitutes a “scientific exchange” by which a manufacturer could, within defined limitations, share data related to an unapproved indication. We believe that H.R. 1703 strikes the right balance between placing reasonable and sound limits on manufacturers and allowing a productive, scientific exchange of data that will benefit patients.

In closing, we thank you for your commitment to this important issue and stand ready to help you advance the Medical Product Communications Act of 2017. Please do not hesitate to contact us should you have any questions or require additional information.

Sincerely,

American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
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