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Dear Colleague:

Please join me in cosponsoring H.R. 1703, the Medical Product Communications Act. This bill clarifies in statute several important concepts that impact how drug and medical device manufacturers can discuss truthful and non-misleading information about their products that is not included in the FDA-approved labeling.

When the Food and Drug Administration (FDA) approves a drug or device, it is authorizing the manufacturer to market the product for specific uses. However, based on their medical expertise and informed by data generated from a variety of sources, doctors often prescribe or administer therapies at different dosages or for other "off-label" uses. Prohibiting manufacturers from responsibly engaging in a meaningful dialogue about such uses is not the right approach. The proposed legislation would clarify the type of communications FDA could consider in determining whether a new intended use had been established by the manufacturer. Specifically, it would exempt scientific exchange from these determinations and enable manufacturers to proactively discuss with health care providers information outside the scope of the FDA-approved labeling.

In the 2011 Supreme Court case *Sorrell v. IMS Health Inc.*, the Court held that First Amendment commercial speech protections extend to medical product manufacturers. Furthermore, in *US v. Caronia* (2012), the Court held that the Food, Drug, and Cosmetic Act does not authorize the FDA to prohibit manufacturers from disseminating truthful, off-label information. Recently, several court cases have challenged FDA's authority to regulate truthful and non-misleading information under 1st Amendment commercial speech protections. It is clear from this influx of litigation that clear rules must be established about what information manufacturers can communicate about their products without the uncertainty of liability. Congress and the FDA are well-suited to make this determination and if we do not take action, this issue will be left for the courts to decipher.

Congress should clarify the statute so this type of scientific exchange between medical product manufacturers and health care decision-makers can occur. Doctors should have the most up-to-date information when caring for their patients and, when done responsibly and in an appropriate context, manufacturers should be able to provide it.

If you wish to cosponsor this bill or if you have any questions, please contact Kristin Seum in Rep. Griffith's office at Kristin.Seum@mail.house.gov. Thank you for your consideration.

Sincerely,



H. MORGAN GRIFFITH
Member of Congress