



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

AUG 3 1 2016

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you for your letter of May 26 regarding the Food and Drug Administration's (FDA) regulation of medical product manufacturer communications, including the proactive dissemination of truthful and non-misleading information that is outside the scope of a product's FDA-approved labeling. I appreciate your interest in this matter.

As representatives from the Department of Health and Human Services (HHS) and FDA have previously discussed with your staff, FDA has been engaging in a comprehensive review of its regulatory framework related to firms' communications about unapproved uses of approved/cleared medical products.

The issues related to manufacturer communication regarding unapproved uses of approved products are numerous and complex. HHS and FDA continue to carefully consider these issues in light of the public health interests at stake. However, we do not believe legislation regarding this issue is necessary at this time.

I am pleased to inform you that, as announced today in the *Federal Register*, FDA has planned a public meeting this fall to hear perspectives and collect additional data from a broad range of stakeholders to help inform FDA and HHS' thinking about these complex and important issues.

Thank you, again, for contacting me concerning this matter. If you have additional questions, please contact Assistant Secretary for Legislation, Jim Esquea, at (202) 690-7627. I will also provide this response to Senator Upton.

Sincerely,

A handwritten signature in black ink that reads "Sylvia M. Burwell".

Sylvia M. Burwell