

United States Senate

WASHINGTON, DC 20510-4804

February 26, 2014

Dr. Mark Taubman
Dean, School of Medicine and Dentistry
University of Rochester Medical Center
601 Elmwood Ave, Box 706
Rochester, NY 14642

Dear Dr. Taubman:

We write regarding reports on the improper relationship between the Food and Drug Administration (FDA) and the pharmaceutical industry. We are deeply troubled by allegations that the FDA gave manufacturers of prescription drugs the opportunity to pay thousands of dollars to the University of Rochester Medical Center (URMC) for the privilege to attend private meetings with FDA officials. The *Washington Post* and the *Milwaukee Journal Sentinel* reported in October of 2013 that each company paid as much as \$25,000-\$35,000 to participate in these pay-to-play meetings, giving them undue influence over FDA's approval process for prescription painkillers.

We have expressed to FDA Commissioner Margaret Hamburg our dismay with these pay-to-play meetings and the role they may have played in FDA's failure to protect and promote public health through the regulation and supervision of prescription painkillers. The FDA's approval process should not compromise patient safety for financial gain.

We are also troubled by the role the pay-to-play meetings may have played in the recent approval of Zohydro ER, a controversial new prescription painkiller. Zohydro ER has up to 10 times as much hydrocodone as Vicodin and Lortab and will come in a formulation that can be easily crushed, snorted and injected. FDA approved Zohydro despite the FDA's own Anesthetic and Analgesic Drug Products Advisory Committee voting 11-2 against approval.

As part of our effort to understand the role played by University of Rochester employees, federal employees and pharmaceutical companies in altering the FDA's approval process for prescription painkillers, please provide the following information:

- 1) Provide a detailed account of all payments/transfers received by your institution from pharmaceutical companies in relation to pain conferences for the period of 2001 to the present, including payments related to IMMPACT, ACTTION and any neuropathic pain conferences. For each payment identified, please provide:
 - a. Name of company making payment;
 - b. Date of payment;
 - c. Amount of payment; and
 - d. Description or purpose of payment.

- 2) Please provide a detailed account of all payments/transfers received by your institution from pharmaceutical companies in relation to pain conferences for the period of 2001 to the present, including payments related to IMMPACT, ACTION and any neuropathic pain conferences. For each expense please provide:
 - a. Name of payee;
 - b. Date of payment;
 - c. Amount of payment; and
 - d. Description or purpose of payment.

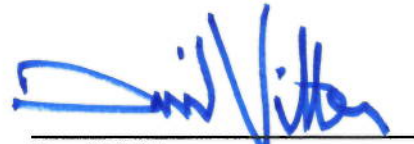
- 3) For each meeting of IMMPACT (including “mini-IMMPACT” meetings and planning meetings), ACTION, and any neuropathic pain conferences please provide:
 - a. Date of meeting;
 - b. Location of meeting;
 - c. List of attendees;
 - d. List of attendees paid honorarium and amount of each honorarium;
 - e. Total cost for meals & beverages;
 - f. Average per person cost for meals & beverages; and
 - g. Detailed account of all expenses paid to support the meeting.

We look forward to hearing from you by no later than March 30, 2014. If you have any questions, please do not hesitate to contact Kirtan Mehta (Senator Manchin) at (202) 224-3528 or Emily Wilkinson (Senator Vitter) at (202) 224-0524.

Sincerely,



Joe Manchin III
United States Senator



David Vitter
United States Senator