

United States Senate

WASHINGTON, DC 20510

April 27, 2017

Scott Gottlieb, MD
Nominee, Commissioner of the Food and Drug Administration
c/o U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Dr. Gottlieb:

In your response to written questions for the record after your nomination hearing before the Senate Health, Education, Labor, and Pensions Committee, you stated that the opioid epidemic was “the biggest public health crisis facing the FDA” and that, if confirmed, addressing this epidemic would be your “highest, immediate priority.”

We agree that immediate action is needed, and that the FDA is a critical partner in this public health fight. However, we are concerned about the disjuncture between these statements and your work as an expert witness, paid to defend the actions of a company that pled guilty to criminal charges that it promoted its fentanyl product for off-label uses other than what the FDA approved.¹

Recently, a *Washington Post* article outlined efforts you took in your former capacity as Deputy Commissioner of the Food and Drug Administration to engage with the Drug Enforcement Administration (DEA) on behalf of a particular company, Cephalon, to increase the amount of fentanyl available for it to manufacture its products.

The request to increase the amount of fentanyl available to Cephalon came while the company was under investigation for illegally pushing doctors to prescribe the drug for off-label uses, such as back pain, rather than its indicated use for severe cancer-related pain. Ultimately, the DEA denied the request, finding that Cephalon and the FDA had no basis for this increased allotment.

According to publicly available court documents, after you left the FDA, you served as an expert witness for Cephalon in class action litigation in federal court in Pennsylvania alleging that it engaged in wrongdoing in connection with its off-label promotion activities for its fentanyl product Actiq.² Your work as an expert witness on Cephalon’s behalf included the preparation and submission of an expert report opining on the propriety of Cephalon’s actions. However, your publicly available financial disclosure statements prepared in connection with the Senate confirmation process does not include detailed information about this work.

¹ <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html>

² See *In re Actiq Sales Marketing and Practices Litig.*, Civil Action No. 07-4492 (PBT), Mem. Op. at 28, 30, 31 (E.D. Pa. July 21, 2014) (Document 421); Mem. Law Opp. Pls.’ Mot. Class Certification at 6, 9, 10, 32 (E.D. Pa. Mar. 27, 2013) (Document 375).


To better understand the nature of your relationship with Cephalon, we respectfully request that you respond to the following questions by the close of business on April 28, 2017:


1. Prior to your appointment as FDA Deputy Commissioner for Medical and Scientific affairs, did you ever provide any services to Cephalon or its subsidiary Anesta? If so, please describe the nature of those services (*e.g.*, direct employment; consulting) and the financial relationship (*e.g.*, cash or other remuneration received).
2. After you left the FDA, did you ever provide any services to Cephalon, its subsidiary Anesta, or its parent company Teva? What was the nature of these services? When did the relationship first start? How long did the relationship last? Please describe the nature of your work, the topics covered, and the financial relationship.
3. Please identify all cases in which you were retained as an expert witness for Cephalon, and who retained you (*i.e.*, Cephalon or the law firm representing it). How much were you paid in each case for your work as Cephalon's expert witness and by whom? How much of that was for preparation of an expert report? Please provide any expert reports or drafts thereof that you prepared on Cephalon's behalf which are not sealed pursuant to a court order or subject to a confidentiality or nondisclosure agreement.

We thank you in advance for your response to these requests. Should you have any questions, please contact Avenel Joseph (Senator Markey) at 202-224-2742, Beth Pearson (Senator Warren) at 202-224-4543, McKenzie Bennett (Senator Hassan) at 202-224-3324, Anna Esten (Senator Whitehouse) at 202-224-2921, or Abigail Duggan (Senator Brown) at 202-224-2315.

Sincerely,


Edward J. Markey
United States Senator


Elizabeth Warren
United States Senator


Margaret Wood Hassan
United States Senator


Sheldon Whitehouse
United States Senator


Sherrod Brown
United States Senator