

March 24, 2009

Via Electronic Transmission

Frank M. Torti, MD, MPH
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Torti:

As a senior member of the United States Senate and the Ranking Member of the Committee on Finance (Committee), I have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the Food and Drug Administration (FDA/Agency). In this capacity, I work to ensure that FDA is completing its mission to protect the public's health and makes responsible use of the public funding provided for medical studies. Decisions made by FDA often form the basis for action taken by the Medicaid and Medicare programs which fall under the exclusive jurisdiction of the Committee.

I am concerned about a recent memorandum you sent to FDA employees warning them of their obligations to keep certain information confidential. While I appreciate the fact that some information, including certain business trade secrets, needs to be protected from unauthorized disclosures, I have serious concerns that your memorandum goes beyond legitimate privacy concerns and appears to run contrary to many statutes protecting executive branch communications with members of Congress.

Specifically, your memorandum notes that certain information acquired from businesses and industry is protected as confidential and may only be disclosed in limited circumstances. Your memorandum cited the Food, Drug, and Cosmetic Act, the Freedom of Information Act (FOIA), the Trade Secrets Act, and the Privacy Act, as well as FDA regulations as the controlling authority for determining when a document or information may be disclosed. You added that FDA employees who violate these provisions may face disciplinary sanctions and criminal liability.

I appreciate your concerns with protecting confidential information from unauthorized disclosures. These protections play an important role in allowing business and industry to work cooperatively with regulatory agencies. However, I am concerned with the timing of your memorandum, given some recent high profile matters concerning your Agency and the release of information that has shown failures in FDA's regulatory mission. My concern is that this recent memorandum could be viewed by some as an effort to chill and/or prevent FDA employees from exercising their rights under whistleblower protection laws to communicate with Congress.

For example, internal FDA documents released recently seem to suggest that lobbying may have influenced the decision in a device approval.^[1] Another internal document shows that

^[1] Mundy, Alicia, "Political Lobbying Drove FDA Process," *The Wall Street Journal*, 6 March 2009.

a physician was removed for inappropriate reasons from a recent safety panel.^[2] In both, cases, I do not believe that Congress would be notified unless whistleblowers spoke up.

Dr. Torti, I have been an outspoken advocate for whistleblowers and have authored numerous whistleblower protection provisions. Whistleblowers are some of the most patriotic people I know—men and women who labor, often anonymously, to let Congress and the American people know when the Government isn't working so we can fix it. As such, it would have been prudent for you to include a section in your memorandum that outlines the interplay between protected confidential and trade secret information and making protected disclosures to Congress and/or Inspectors General in accordance with the whistleblower protection laws. Absent such a discussion, many FDA employees could take this memo to mean that they could be criminally sanctioned for providing information to Congress.

As you may be aware, 18 U.S.C. § 1505 states, in pertinent part:

Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress--

Shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both.

Additionally, denying or interfering with employees' rights to furnish information to Congress is also against the law. I have attached another copy of 5 U.S.C. § 7211 to this letter for your reference. That law states:

The right of employees, individually or collectively, to petition Congress or a Member of Congress, or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied.

Finally, federal officials who deny or interfere with employees' rights to furnish information to Congress are not entitled to have their salaries paid by taxpayers' dollars. I have attached a copy of P.L. 111-5 § 714 to this letter for your reference, which states:

No part of any appropriation contained in this or any other Act shall be available for the payment of the salary of any officer or employee of the Federal Government, who -

^[2] Russel, John, "Lilly faces inquiries over drugs Alimta, Effient," *IndyStar.com*, 28 Feb 2009.

- (1) prohibits or prevents, or attempts or threatens to prohibit or prevent, any other officer or employee of the Federal Government from having any direct oral or written communication or contact with any Member, committee, or subcommittee of the Congress in connection with any matter pertaining to the employment of such other officer or employee or pertaining to the department or agency of such other officer or employee in any way, irrespective of whether such communication or contact is at the initiative of such other officer or employee or in response to the request or inquiry of such Member, committee, or subcommittee; or
- (2) removes, suspends from duty without pay, demotes, reduces in rank, seniority, stats, pay, or performance of efficiency rating, denies promotion to, relocates, reassigns, transfers, disciplines, or discriminates in regard to any employment right, entitlement, or benefit, or any term or condition of employment of, any other officer or employee of the Federal Government, or attempts or threatens to commit any of the foregoing actions with respect to such other officer or employee, by reason of any communication or contact of such other officer or employee with any Member, committee, or subcommittee of the Congress as described in paragraph (1).

FDA employees have the right to talk to Congress and to provide Congress with information free and clear of Agency influence. Further, these employees have the right to be free from fear of retaliation or reprisal. You should review these important statutes and reevaluate the message sent by your memorandum. I believe that you should take the further step of issuing a second memorandum to FDA employees outlining their rights and whistleblower protections, as well as outlining the FDA's responsibilities for respecting those protected disclosures. Such a memorandum would go a long way toward ensuring that the FDA remains "committed to the principles of open Government and transparency" as you stated in your memorandum.

If you have any questions please contact my Committee staff, Emilia DiSanto or Paul Thacker at (202) 224-4515. Any formal correspondence should be sent electronically in PDF searchable format to Brian_Downey@finance-rep.senate.gov.

Sincerely,

Charles E. Grassley
Ranking Member